concentrated orange juice (21 CFR 146.150), orange juice with preservative (21 CFR 146.152), concentrated orange juice for manufacturing (21 CFR 146.153) and concentrated orange juice with preservative (21 CFR 146.154), to provide for inclusion of juice from the hybrid species described as 1/2 *C. sinensis* X 3/8 *C. reticulata* X 1/8 *C. paradisi* (USDA Selection:1–100–29: 1972 Whitmore Foundation Farm) in the same manner as the juice from oranges of the species C. sinensis, i.e., without limits on the amount of juice from the hybrid that may be used in the final product.

III. Economic Impact

FDA has examined the economic implications of this final rule to amend certain standards of identity for orange juice products in 21 CFR part 146 according to the standards in Executive Orders 12291 and 12612, and by the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601).

FDA noted in the proposed rule that providing for the use of the juice of the Ambersweet hybrid in standardized orange juice products in part 146 would permit increased variety of orange juice products to consumers and would provide increased flexibility in the manufacture of orange juice products to both large and small entities. Thus, FDA tentatively concluded that the regulation would have zero costs associated with it. FDA has received no new information or comments that would alter the tentative finding that it set out in the proposed rule that: (1) There is no substantive economic issue in this rulemaking, and (2) this is not a major rule.

Therefore, the agency concludes that this final rule is not a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act (Pub. L. 96–354), FDA has also determined that this final rule will not have a significant adverse impact on a substantial number of small businesses. Finally, because this regulation modifies a food standard, and food standards are given preemptive effect under section 403A(a)(1) of the act (21 U.S.C. 343–1(a)(1)), FDA finds that there is no substantial federalism issue which would require an analysis under Executive Order 12612.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(b)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 146

Food grades and standards, Fruit juices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 146 is amended as follows.

PART 146—CANNED FRUIT JUICES

1. The authority citation for 21 CFR part 146 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

2. Section 146.135 is amended by revising paragraph (a) to read as follows:

§ 146.135 Orange juice.

(a) Orange juice is the unfermented juice obtained from mature oranges of the species *Citrus sinensis* or of the citrus hybrid commonly called "Ambersweet" (1/2 *Citrus sinensis* X 3/8 *Citrus reticulata* X 1/8 *Citrus paradisi* (USDA Selection:1–100–29: 1972 Whitmore Foundation Farm)). Seeds (except embryonic seeds and small fragments of seeds that cannot be separated by current good manufacturing practice) and excess pulp are removed. The juice may be chilled, but it is not frozen.

* * * * *

3. Section 146.140 is amended by revising the first sentence in paragraph (a) to read as follows:

§ 146.140 Pasteurized orange juice.

(a) Pasteurized orange juice is the food prepared from unfermented juice obtained from mature oranges as specified in § 146.135, to which may be added not more that 10 percent by volume of the unfermented juice obtained from mature oranges of the species *Citrus reticulata* or *Citrus reticulata* hybrids (except that this limitation shall not apply to the hybrid species described in § 146.135). * * *

* * * * *

4. Section 146.141 is amended by revising the first sentence in paragraph (a) to read as follows:

§ 146.141 Canned orange juice.

(a) Canned orange juice is the food prepared from orange juice as specified in § 146.135 or frozen orange juice as specified in § 146.137, or a combination of both, to which may be added not more than 10 percent by volume of the unfermented juice obtained from mature oranges of the species *Citrus reticulata* or *Citrus reticulata* hybrids (except that this limitation shall not apply to the hybrid species described in § 146.135).

* * *

* * * * *

5. Section 146.146 is amended by revising the first two sentences in paragraph (a) to read as follows:

§ 146.146 Frozen concentrated orange juice.

(a) Frozen concentrated orange juice is the food prepared by removing water from the juice of mature oranges as provided in § 146.135, to which may be added unfermented juice obtained from mature oranges of the species *Citrus reticulata*, other *Citrus reticulata* hybrids, or of *Citrus aurantium*, or both. However, in the unconcentrated blend, the volume of juice from *Citrus reticulata* or *Citrus reticulata* hybrids shall not exceed 10 percent (except that this limitation shall not apply to the hybrid species described in § 146.135) and from *Citrus aurantium* shall not exceed 5 percent. * * *

* * * * *

6. Section 146.151 is amended by revising the second sentence in paragraph (a) to read as follows:

§ 146.151 Orange juice for manufacturing.

(a) * * * It is prepared from unfermented juice obtained from oranges as provided in § 146.135, except that the oranges may deviate from the standards for maturity in that they are below the minimum for Brix and Brix-acid ratio for such oranges, and to which juice may be added not more than 10 percent by volume of the unfermented juice obtained from oranges of the species *Citrus reticulata* or *Citrus reticulata* hybrids (except that this limitation shall not apply to the hybrid species described in § 146.135). * * *

* * * * *

Dated: November 1, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92–29519 Filed 12–4–92; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[T.D. 8451]

RIN 1545-AR03

Employee Business Expenses—Reporting and Withholding on Employee Business Expense Reimbursements and Allowances

AGENCY: Internal Revenue Service, Treasury.

ACTION: Temporary and final regulations.

SUMMARY: This document contains final regulations relating to the taxation of and reporting and withholding on employee business expense reimbursements and other expense allowance arrangements. The regulations affect employees who receive payments and payors who make payments under reimbursement or other expense allowance arrangements. The guidance is the same as that set forth in temporary regulations published in 1989 and 1990.

EFFECTIVE DATE: December 7, 1992.

FOR FURTHER INFORMATION CONTACT: Marianna Dyson, at (202) 622-4606 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Temporary regulations (TD 8189) under § 1.62-1T were first published in the Federal Register on March 28, 1988 (53 FR 9873). A cross-reference notice of proposed rulemaking (LR-97-96) was published in the Federal Register on the same day. Paragraphs (c) and (f) of section 1.62-1T of these temporary regulations were amended by temporary regulations (TD 8276) published in the Federal Register on December 12, 1989 (54 FR 51024). Paragraph (c) of section 1.62-1T was subsequently amended by temporary regulations (TD 8324) published in the Federal Register on December 17, 1990 (55 FR 51688). Cross-reference notices of proposed rulemaking (EE-8-89) were also published. Temporary regulations (TD 8004) under § 1.162-25T were first published in the Federal Register on January 7, 1985 (50 FR 747). A cross-reference notice of proposed rulemaking (LR-216-84) was published in the Federal Register on the same day. Section 1.162-25T(b) of these temporary regulations were amended by temporary regulations (TD 8276) published in the Federal Register on December 12, 1989 (54 FR 51026). A cross-reference notice of proposed rulemaking (EE-8-89) was also published. Temporary regulations (TD 8061) under § 1.274-5T were first published in the Federal Register on November 6, 1985 (50 FR 46006). Section 1.274-5T(g) of these temporary regulations was amended by temporary regulations (TD 8276) published in the Federal Register on December 12, 1989 (54 FR 51024). A cross-reference notice of proposed rulemaking (EE-8-89) was also published. Written comments were received from the public on the proposed regulations.

Under section 7805(e) of the Internal Revenue Code, any temporary regulation issued after November 20, 1988, expires within 3 years after the date of its issuance. This Treasury decision adopts in final form portions of the temporary regulations that would otherwise expire within three years after the date of their issuance and revises cross references to these portions.

Special Analyses

It has been determined that these rules are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and, therefore, a final Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these regulations is Marianna Dyson, Office of the Associate Chief Counsel (Employee Benefits and Exempt Organizations), Internal Revenue Service. However, personnel from other offices of the Service and Treasury Department participated in their development.

List of Subjects in 26 CFR 1.61-1 Through 1.280H-1T

Bonds, Income taxes, Reporting and recordkeeping requirements.

Adoption of the Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.62-1 is added to read as follows:

§ 1.62-1 Adjusted gross income.

(a) [Reserved]

(b) [Reserved]

(c) *Deduction allowable in computing adjusted gross income.* The deductions specified in section 62(a) for purposes of computing adjusted gross income are—

(1) Deductions set forth in § 1.62-1T(c); and

(2) Deductions allowable under part VI, subchapter B, chapter 1 of the Internal Revenue Code, (section 161 and following) that consist of expenses paid or incurred by the taxpayer in connection with the performance of services as an employee under a reimbursement or other expense allowance arrangement (as defined in § 1.62-2) with his or her employer. For the rules pertaining to expenses paid or incurred in taxable years beginning before January 1, 1989, see § 1.62-1T (c)(2) and (f) (as contained in 26 CFR part 1 (§§ 1.61 to 1.169) revised April 1, 1992).

(d) through (h) [Reserved]

(i) *Effective date.* Paragraph (c) of this section is effective for taxable years beginning on or after January 1, 1989.

Par. 3. Section 1.62-1T is amended as follows:

1. Paragraphs (c)(2) and (f) are removed and reserved.

2. In paragraph (e)(1), the parenthetical "(as defined in paragraph (f) of this section)" in the second sentence is removed.

Par. 4. Section 1.62-2 is amended as follows:

1. In the first sentence of paragraph (c)(1), the reference "§§ 1.62-1T and 1.62-2" is removed and "§§ 1.62-1, 1.62-1T, and 1.62-2" is added in its place.

2. In the third sentence of paragraph (c)(5), the reference "§ 1.274-5T or 1.162-17" is removed and "§§ 1.274-5T and 1.274(d)-1 or § 1.162-17" is added in its place.

3. In paragraph (d)(3)(ii), the reference "§ 1.274-5T(g)" is removed and "§ 1.274(d)-1" is added in its place.

4. In the sixth and eighth sentences of paragraph (e)(2), the reference "§ 1.274-5T(g)" is removed and "§ 1.274(d)-1" is added in its place.

5. In paragraph (h)(2)(i)(B)(*1*), the reference "§ 1.274-5T(g) or (j)" is

removed and "§ 1.274(d)–1 or § 1.274–5T(j)" is added in its place.

Par. 5. Section 1.132–5 is amended as follows:

1. In the last sentence of paragraph (b)(1)(iv), the reference "§ 1.162–25T" is removed and "§§ 1.162–25 and 1.162–25T" is added in its place.

Par. 6. Section 1.162–25 is added to read as follows:

§ 1.162–25 Deductions with respect to noncash fringe benefits.

(a) [Reserved]

(b) *Employee.* If an employer provides the use of a vehicle (as defined in § 1.61–21(e)(2)) to an employee as a noncash fringe benefit and includes the entire value of the benefit in the employee's gross income without taking into account any exclusion for a working condition fringe allowable under section 132 and the regulations thereunder, the employee may deduct that value multiplied by the percentage of the total use of the vehicle that is in connection with the employer's trade or business (business value). For taxable years beginning before January 1, 1990, the employee may deduct the business value from gross income in determining adjusted gross income. For taxable years beginning on or after January 1, 1990, the employee may deduct the business value only as a miscellaneous itemized deduction in determining taxable income, subject to the 2-percent floor provided in section 67. If the employer determines the value of the noncash fringe benefit under a special accounting rule that allows the employer to treat the value of benefits provided during the last two months of the calendar year or any shorter period as paid during the subsequent calendar year, then the employee must determine the deduction allowable under this paragraph (b) without regard to any use of the benefit during those last two months or any shorter period. The employee may not use a cent-per-mile valuation method to determine the deduction allowable under this paragraph (b).

Par. 7. Section 1.162–25T is amended by removing and reserving paragraph (b).

Par. 8. Section 1.274(d)–1 is added to read as follows:

§ 1.274(d)–1 Substantiation requirements.

(a) *Substantiation by reimbursement arrangements or per diem, mileage, and other traveling allowances*—(1) *In general.* The Commissioner may, in his discretion, prescribe rules in pronouncements of general applicability under which allowances for expenses described in paragraph (a)(2) of this section will, if in accordance with reasonable business practice, be regarded as equivalent to substantiation by adequate records or other sufficient evidence for purposes of § 1.274–5T(c) of the amount of such expenses and as satisfying, with respect to the amount of such expenses, the requirements of an adequate accounting to the employer for purposes of § 1.274–5T(f)(4). If the total allowance received exceeds the deductible expenses paid or incurred by the employee, such excess must be reported as income on the employee's return. See § 1.274–5T(j) relating to the substantiation of meal expenses while traveling away from home.

(2) *Allowances for expenses described.* An allowance for expenses is described in this paragraph (a)(2) if it is a—

(i) Reimbursement arrangement covering ordinary and necessary expenses of traveling away from home (exclusive of transportation expenses to and from destination);

(ii) Per diem allowance providing for ordinary and necessary expenses of traveling away from home (exclusive of transportation costs to and from destination); or

(iii) Mileage allowance providing for ordinary and necessary expenses of local travel and transportation while traveling away from home.

(3) *Limitation.* A mileage allowance described in paragraph (a)(2)(iii) of this section is available only to the owner of a vehicle.

(b) [Reserved]

Par. 9. Section 1.274–5T is amended as follows:

1. In paragraph (e)(1)(ii), the reference "§ 1.61–2T(e)(2)" is removed and "§ 1.61–21(e)(2)" is added in its place and the reference "§ 1.162–25T" is removed and "§§ 1.162–25 and 1.162–25T" is added in its place.

2. Paragraph (g) is revised.

3. In paragraph (l), the reference to "§ 1.61–2T(d)(1)(ii) and § 1.61–2T(e)(2)" is removed and "§ 1.61–21(d)(1)(ii) and § 1.61–21(e)(2)" is added in its place.

4. In paragraph (m), the reference "§ 1.132–5T(h)" is removed and "§ 1.132–5(h)" is added in its place.

5. In paragraph (m), the reference "§ 1.162–25T(b)" is removed and "§ 1.162–25(b)" is added in its place.

6. The revision to paragraph (g) reads as follows:

§ 1.274–5T Substantiation requirements (temporary).

* * * * *

(g) Substantiation by reimbursement arrangements or per diem, mileage, and other traveling allowances. For guidance, see § 1.274(d)–1.

* * * * *

Shirley D. Peterson,

Commissioner of Internal Revenue.

Approved: December 1, 1992.

Fred T. Goldberg, Jr.,

Assistant Secretary of the Treasury.

[FR Doc. 92–29700 Filed 12–4–92; 8:45 am]

BILLING CODE 4830–01–M

DEPARTMENT OF JUSTICE

28 CFR Part 68

[Order No. 1635–92]

Executive Office for Immigration Review; Rules of Practice and Procedure for Administrative Hearings Before Administrative Law Judges in Cases Involving Allegations of Unlawful Employment of Aliens and Unfair Immigration-Related Employment Practices

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule sets forth amendments to rules of practice and procedure for administrative hearings. These amendments are necessary to bring the practices and procedures established into conformity with the provisions of the Immigration Act of 1990.

EFFECTIVE DATE: This final rule is effective December 7, 1992.

FOR FURTHER INFORMATION CONTACT: Gerald S. Hurwitz, Counsel to the Director, Executive Office for Immigration Review, suite 2400, 5107 Leesburg Pike, Falls Church, Virginia 22041, (703) 305–0470.

SUPPLEMENTARY INFORMATION: Sections 274A, 274B, and 274C of the INA require that hearings be held before Administrative Law Judges in cases involving allegations of:

(1) The unlawful hiring, or recruiting or referring for a fee, for employment in the United States, of aliens when the hiring person or entity knows that the aliens are unauthorized to work in the United States; or of any individual when the hiring person or entity fails to comply with the employment eligibility verification requirements (8 U.S.C. 1324a(a)(1));

(2) The continued employment of aliens in the United States when the hiring person or entity knows that the aliens are or have become unauthorized for such employment (8 U.S.C. 1324a(a)(2));

(3) The unlawful imposition, in the hiring, recruiting, or referring for

employment of any individual, of any requirement that the individual post bond or security, pay or agree to pay any amount, or otherwise guarantee or indemnify against any potential liability under 8 U.S.C. 1324a, for unlawful hiring, recruiting or referring of such individual (8 U.S.C. 1324a(g));

(4) Unfair immigration-related employment practices (8 U.S.C 1324b); and

(5) Knowing participation by any person or entity in activities involving fraudulent creation or use of documents for the purposes of satisfying, or complying with, a requirement of the INA (8 U.S.C 1324c).

On November 24, 1987, the Department of Justice published an interim final rule establishing administrative practices and procedures to implement section 274A and 274B of the INA. 52 FR 44972 (Nov. 24, 1987). After receiving comments, the Department published the final rule on November 24, 1989. 54 FR 48593 (Nov. 24, 1989). That rule governed all cases properly brought before an Administrative Law Judge that comply with the requirements of the INA. Then, on November 28, 1990, Congress enacted the Immigration Act of 1990, which amended section 274A and 274B of the INA, and added section 274C. These amendments necessitated certain revisions to the practices and procedures established by Part 68, which were set forth in the interim rule with request for comments, published October 3, 1991. 56 FR 50049. The comment period ended on November 4, 1991. A total of twenty-six specific comments were received and considered in preparing this final rule. Changes were made in the final rule based upon consideration of the comments received and experience gained by the Office of the Chief Administrative Hearing Officer (OCAHO) in implementing the hearing procedures. What follows is a section-by-section analysis of the final revisions to the interim rule and a discussion of the comments concerning the sections to which they apply.

Section 68.2 added a new subsection (i) which defines "entry" of an order for the purposes of determining when the sixty (60) day time period begins for appeal to a federal circuit court of appeals under section 274B(i)(1) of the INA. The Tenth Circuit, in *Mesa Airlines* v. *United States*, 951 F.2d 1186 (10th Cir. 1991), interpreted the word "entry" to mean the date the Administrative Law Judge signed and dated the order. Accordingly, the rule has adopted this definition. Likewise, subsection (k) of § 68.2 defines "issued" in the same manner for cases arising under sections 274A and 274C of the INA.

Section 68.2 added a new subsection (n) which defines "ordinary mail." This was the result of one commenter's suggestion that § 68.8(c)(2) be amended to specify that the reference to "mail" in that section is a reference to "ordinary mail" (see discussion of § 68.8 below.)

A number of commenters suggested that § 68.2(t)(2) (formerly § 68.2(r)(2)) was misleading in that it did not include the entire statutory definition of intimidation or retaliation under section 274B of the INA. After consideration of these comments, the OCAHO determined that the scope of § 68.2(t)(2) was sufficiently clear in its present form.

The reference to "section 274B(a)(5) of the INA" in § 68.2(t)(2) clearly indicates that it is also an unfair immigration-related employment practice to intimidate, threaten, coerce or retaliate against any individual for the purposes for interfering with any right or privilege secured under section 274B of the INA or because the individual intends to file or has filed a charge or a complaint, testified, assisted, or participated in any manner in an investigation, proceeding or hearing under section 274B of the INA.

Section 68.3 was reorganized to include the addition of a new subsection (c) which allows the Chief Administrative Hearing Officer or the Administrative Law Judge to direct a party to execute service in circumstances where there is difficulty with perfecting service.

Section 68.8(c)(2) was amended to clarify that additional time is available for a response to a pleading, notice or other document when such documents are received by a party through "ordinary" mail only. This change was made as a result of a suggestion by one commenter that the subsection make clear that the additional time would not be granted for documents received by overnight mail, facsimiles, registered mail, certified mail or any other means of expedited service. The subsection was also amended to note that the formula for additional response time is inapplicable if the Chief Administrative Hearing Officer or the Administrative Law Judge specifies a compliance date, other than the date prescribed by the rule.

Section 68.25(b) was amended to require that when a non-party is subpoenaed, notice of the subpoena must be given by the requestor to all parties. In an investigation under section 274B of the INA, where a complaint has not been filed, the notice must be given to the charging party, the party who is charged with an unfair immigration-related employment practice, and the Office of Special Counsel. This amendment is the result of one commenter's suggestion that the principal targets of an investigation should have notice of a subpoena that is received by another person or entity.

A new subsection (d) of § 68.25 was added, which gives a party standing to challenge a subpoena issued to a non-party if the party can claim a personal right or privilege in the discovery sought. This amendment is also in response to a commenter's suggestion to make clear that parties have standing to challenge a subpoena issued to a non-party.

A number of commenters contended that § 68.25 should be revised to require that a request for a subpoena be in writing, in order to provide a procedural safeguard against abuse of the subpoena process. This suggestion was rejected as the rule provides a mechanism to prevent abuse, *i.e.*, the petition to revoke or modify the subpoena. The same commenters also requested that § 68.25 be amended to allow 30 days for filing a petition to revoke or modify a subpoena, rather than the ten (10) days currently provided for in the rule. This suggestion was rejected because the current ten (10) day limit expedites the proceeding and experience has shown that the ten (10) day limit has not been an undue burden on the recipient. Moreover, if the circumstances of a particular case indicate that additional time would be justified or appropriate, § 68.25(c) gives the Administrative Law Judge the discretion to set another deadline.

One commenter suggested that § 68.25 be revised to require that the subpoena form notify the recipient of the time limit and procedures involved for filing a petition to revoke or modify the subpoena. This proposed change to the rule was deemed unnecessary since new subpoena forms to be issued by OCAHO will notify the recipient of the time limit and procedure for filing a petition to revoke or modify.

Section 68.26 was amended to allow the Chief Administrative Hearing Officer to reassign a case already assigned to an Administrative Law Judge for administrative purposes.

With respect to § 68.33, a number of commenters expressed concern that allowing the request for a hearing to constitute a notice of appearance would require an attorney to continue representation of the respondent. Clearly, an attorney is free to notify the Chief Administrative Hearing Office and/or the Administrative Law Judge

that, notwithstanding a request for a hearing, the attorney is withdrawing from the case. Additionally, in response to another comment, it is noted that an entry of appearance before an Administrative Law Judge pursuant to sections 274A, 274B, and 274C of the INA constitutes an entry of appearance before this agency only, and not for other proceedings before the Immigration and Naturalization Service or the Executive Office for Immigration Review.

Section 68.37(b)(2)(ii) was amended to clarify that the Administrative Law Judge has discretion to modify the time period within which a party may show good cause for failure to appear at a hearing or face possible dismissal of a complaint or a request for hearing on grounds of abandonment. The current specification of ten (10) days in which to show good cause for failure to appear is not intended as a jurisdictional time limit. This change is the result of comments expressing concern that the current ten (10) days for compliance is insufficient.

Section 68.52(a) was revised to allow the Administrative Law Judge to require the parties to file post-hearing briefs or supplementary documents. The previous version appeared to allow the parties total discretion even when an Administrative Law Judge requests such filings.

Section 68.52(c)(1)(v) was amended to require an Administrative Law Judge's order to impose a civil penalty in the case of a violation under section 274A(g)(1) of the INA, the prohibition against indemnity bonds. One commenter noted that the rule contained permissive language ("may"), which contravened the statute which contains mandatory language ("shall"). The rule has been revised to mirror the statutory language at section 274A(g)(1) of the INA.

Section 68.52(c)(2)(i)(K) has been revised to include additional remedies for unfair immigration-related employment practice cases in which an employer requests more or additional documents than are required under section 274A(b) of the INA or refuses to honor documents that reasonably appear to be genuine. See section 274B(a)(6) of the INA. A number of commenters noted that the rule, in addition to imposing statutory civil penalties, should also provide for the imposition of rehiring and back pay liability for such documentation abuses. Thus, 68.52(c)(2)(i)(K) now clearly indicates that the remedies set out in section 274B(g)(2)(B)(i), (ii), (iii), (iv)(IV), (v), (vi), (vii) and (viii) all apply to document abuse cases under section 274B(a)(6) of the INA.

Some commenters stated that the supplementary information regarding § 68.52(c)(4) was ambiguous in that the rule did not reflect that motions to amend an Administrative Law Judge's decision and order in cases arising under section 274A or 274C of the INA on substantive issues are permitted. This interpretation is incorrect. Motions to substantively amend orders are not contemplated in cases arising under section 274A and section 274C of the INA. However, § 68.52(c)(4) was amended to clarify that a party seeking a substantive change to an order should file a request for review with the Chief Administrative Hearing Officer, rather than file a motion for reconsideration with the Administrative Law Judge. Additionally, the Chief Administrative Hearing Officer could also correct a substantive error in section 274A and 274C cases through discretionary review based on existing rules. The other amendment to this subsection would allow for substantive changes to Administrative Law Judges' orders in section 274B cases. The reason for this amendment is that an Administrative Law Judge should not be prevented from substantively changing an order within sixty (60) days when the Chief Administrative Hearing Officer has no review authority. Thus, when an error comes to the attention of an Administrative Law Judge within the requisite sixty (60) days, this amendment would obviate the need to appeal to the Court of Appeals for the appropriate circuit.

Section 68.53(a)(1) is amended to make clear that when a party requests a review of a final decision and order of an Administrative Law Judge, and the Chief Administrative Hearing Officer decides not to modify or vacate the order, the Chief Administrative Hearing Officer is not required to issue an order affirming the Administrative Law Judge's order. The Chief Administrative Hearing Officer must issue an order only if he is vacating or modifying the Administrative Law Judge's decision and order. See sections 274A(e)(7) and 274C(d)(4) of the INA.

Finally, this rule does not change or take away rights which were established in the statute or earlier rules of practice and procedure. Therefore, this rule is effective on the date of publication.

Moreover, in accordance with 5 U.S.C. 605(b), the Attorney General certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule is not considered to be a major rule within the meaning of section 1(b) of Executive Order No. 12291, nor does it have Federalism implications warranting the preparation of a Federalism Assessment in accordance with section 6 of Executive Order No. 12612. The Attorney General has certified to the Office of Management and Budget that these final regulations meet the applicable standards provided in sections 2(a) and 2(b)(2) of Executive Order No. 12778.

List of Subjects in 28 CFR Part 68

Administrative practice and procedure, Aliens, Citizenship and naturalization, Civil rights, Discrimination in employment, Employment, Equal employment opportunity, Immigration, Nationality, Non-Discrimination.

Accordingly, the interim rule amending 28 CFR part 68 which was published at 56 FR 50049–50058 on October 3, 1991, is adopted as a final rule with the following changes:

PART 68—RULES OF PRACTICE AND PROCEDURE FOR ADMINISTRATIVE HEARINGS BEFORE ADMINISTRATIVE LAW JUDGES IN CASES INVOLVING ALLEGATIONS OF UNLAWFUL EMPLOYMENT OF ALIENS AND UNFAIR IMMIGRATION-RELATED EMPLOYMENT PRACTICES

1. The authority citation for part 68 is revised to read as follows:

Authority: 5 U.S.C. 301, 554; 8 U.S.C. 1103, 1324a, 1324b, and 1324c.

2. Section 68.2 is amended by:

(a) Redesignating paragraphs (i), (j), (k), and (l) through (q) as paragraphs (j), (l), (m), and (o) through (t), respectively; and

(b) New paragraphs (i), (k), and (n) are added to read as follows:

§ 68.2 Definitions.

* * * * *

(i) *Entry* as used in section 274B(i)(1) of the INA means the date the Administrative Law Judge signed the order;

* * * * *

(k) *Issued* as used in section 274A(e)(8) and section 274C(d)(5) of the INA means the date the Administrative Law Judge signed the order;

* * * * *

(n) *Ordinary mail* refers to the mail service provided by the United States Postal Service using only standard postage fees, exclusive of special systems, electronic transfers, and other means which have the effect of providing expedited service;

* * * * *

3. Section 68.3 is amended by:

(1) Designating the introductory text as paragraph (a);

(2) Redesignating paragraphs (a), (b), and (c) as paragraphs (1), (2), and (3) respectively;

(3) Redesignating paragraph (d) as paragraph (b);

(4) Adding a new paragraph (c) to read as follows:

§ 68.3 Service of complaint, notice of hearing, written orders, and decisions.

* * * * *

(c) In circumstances where the Office of the Chief Administrative Hearing Officer or the Administrative Law Judge encounter difficulty with perfecting service the Chief Administrative Hearing Officer or the Administrative Law Judge may direct that a party execute service of process.

§ 68.5 [Amended]

4. Section 68.5(b) is amended by:

(a) Adding the phrase "In section 274B cases, pursuant to section 554 of title 5, United States Code," to the beginning of the introductory phrase and before the words, "Due regard shall be given".

(b) Correcting the word "Section" in the second sentence to read "Sections".

§ 68.6 [Amended]

5. Section 68.6(a) is corrected by changing the word "others" in the second sentence to read "other".

§ 68.8 [Amended]

6. Section 68.8(c)(2) is amended by inserting the word "ordinary" before the word "mail" and by adding at the end of the sentence the phrase "unless the compliance date is otherwise specified by the Chief Administrative Hearing Officer or the Administrative Law Judge."

§ 68.23 [Amended]

7. Section 68.23(c)(6) is amended by removing the reference to § 68.25(d) and inserting in its place § 68.25(e).

8. Section 68.25 is amended by:

(a) Revising paragraph (b);

(b) Redesignating paragraph (d) as paragraph (e); and

(c) Adding a new paragraph (d) to read as follows:

§ 68.25 Subpoenas.

* * * * *

(b) The subpoena shall identify the person or things subpoenaed, the person to whom it is returnable and the place, date, and time at which it is returnable; or the subpoena shall identify the nature of the evidence to be examined and copied, and the date and time when access is requested. Where a non-party is subpoenaed, the requestor of the subpoena must give notice to all parties, or if no complaint has been filed, then notice shall be given to individuals or entities who have been charged with an unfair immigration-related employment practice under section 274B of the INA, the individual initiating the alleged unfair immigration-related employment practice, and the Office of Special Counsel. For purposes of this subsection, the receipt of the subpoena or a copy of the subpoena shall serve as the notice.

* * * * *

(d) A party shall have standing to challenge a subpoena issued to a non-party if the party can claim a personal right or privilege in the discovery sought.

* * * * *

§ 68.26 [Amended]

9. Section 68.26 is amended by removing the word "will" and replacing it with the word "shall" and by adding the following sentence after the phrase "shall be designated by the Chief Administrative Hearing Officer.": "The Chief Administrative Hearing Officer may reassign a case previously assigned to an Administrative Law Judge to promote administrative efficiency."

§ 68.28 [Amended]

10. Section 68.28(a) is amended by removing in the introductory paragraph the phrase "necessary to the conduct of fair" and inserting in its place the phrase "necessary to conduct fair".

* * * * *

11. Section 68.37 is amended by:

(a) Removing in paragraph (c) the reference to § 68.8(b) and adding in its place the reference § 68.9(b).

(b) Revising paragraph (b)(2)(ii) to read as follows:

§ 68.37 Waiver of right to appear and failure to participate or to appear.11

* * * * *

(b) * * *

(2) * * *

(ii) Within ten (10) days after the time for hearing or within such other period as the Administrative Law Judge may allow, such party does not show good cause for such failure to appear.

* * * * *

§ 68.43 [Amended]

12. Section 68.43 is amended by revising the heading in paragraph (c) to read as follows: *"Substitution of copies for original exhibits".*

§ 68.48 [Amended]

13. Section 68.48(a) is amended by revising the reference to § 68.12 to § 68.14.

14. Section 68.52 is amended by:

(a) In paragraph (a), revising the phrase "a party may file proposed findings of fact," to read "the Administrative Law Judge may require the parties to file proposed findings of fact," and by replacing the phrase "and order together with a supporting brief" to "and orders together with supporting briefs";

(b) In paragraph (c)(1)(v), by removing the word "may" after the phrase "the order" and adding in its place the word "shall";

(c) In paragraph (c)(2)(i)(K), by adding the phrase "or to order any of the remedies listed as paragraphs (c)(2)(i)(A) through (c)(2)(i)(G) above" at the end of the paragraph;

(d) In paragraph (c)(2)(ii), by adding the phrase "of the INA" to the end of the last sentence;

(e) Revising paragraph (c)(4) to read as follows:

§ 68.52 Decision and Order of the Administrative Law Judge.

* * * * *

(c)* * *

(4) *Corrections to orders.* An Administrative Law Judge may, in the interest of justice, correct any clerical mistakes or typographical errors contained in a decision and order issued in a case arising under section 274A or 274C of the INA at any time within thirty (30) days after the issuance of the decision and order. Changes other than clerical mistakes or typographical errors will be considered in cases arising under sections 274A and 274C of the INA by filing a request for review to the Chief Administrative Hearing Officer by a party under § 68.53, or the Chief Administrative Hearing Officer may exercise discretionary review to make such changes pursuant to § 68.53. In cases arising under section 274B of the INA, an Administrative Law Judge may correct any substantive, clerical, or typographical errors or mistakes in a decision and order at any time within sixty (60) days after the issuance of the decision and order.

15. Section 68.53 is amended by:

(a) Revising the word "section" in the introductory text of paragraph (a) to read, "sections";

(b) Adding to the end of paragraph (a)(1) a new sentence to read as follows:

§ 68.53 Administrative and Judicial review.

* * * * *

(a) * * *

(1) * * * However, the Chief Administrative Hearing Officer is not obligated to issue an order unless the Administrative Law Judge's order is modified or vacated.

* * * * *

Dated: November 18, 1992.

William P. Barr,

Attorney General.

[FR Doc. 92-28868 Filed 12-4-92; 8:45 am]

BILLING CODE 1531-26-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[SW-FRL-4542-8]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Final Exclusion

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) today is granting a final exclusion from the lists of hazardous wastes contained in EPA regulations for certain solid waste generated at POP Fasteners (POP), a division of Black and Decker Corporation, located in Shelton, Connecticut. This action responds to a delisting petition submitted under those regulations that allow any person to petition the Administrator to modify or revoke any provision of certain hazardous waste regulations of the Code of Federal Regulations, and specifically provide generators the opportunity to petition the Administrator to exclude a waste on a "generator-specific" basis from the hazardous waste lists.

EFFECTIVE DATE: December 7, 1992.

ADDRESSES: The public docket for this final rule is located at the U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, and is available for viewing (room M2427) from 9 a.m. to 4 p.m., Monday through Friday, excluding Federal holidays. Call (202) 260-9327 for appointments. The reference number for this docket is "F-92-PFEF-FFFFF." The public may copy material from any regulatory docket at no cost for the first 100 pages, and at $0.15 per page for additional copies.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA Hotline, toll free at (800) 424-9346, or at (703) 920-9810. For technical information concerning this notice, contact Shen-yi Yang, Office of Solid Waste (OS-333), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, (202) 260-1436.

SUPPLEMENTARY INFORMATION:

I. Background

A. Authority

Under §§ 260.20 and 260.22, facilities may petition the Agency to remove their wastes from hazardous waste control by excluding them from the lists of hazardous wastes contained at §§ 261.31 and 261.32. Petitioners must provide sufficient information to EPA to allow the Agency to determine that: (1) The waste to be excluded is not hazardous based upon the criteria for which it was listed, and (2) no other hazardous constituents or factors that could cause the waste to be hazardous are present in the wastes at levels of regulatory concern.

B. History of This Rulemaking

POP Fasteners, located in Shelton, Connecticut, petitioned the Agency to exclude from hazardous waste control its F006 metal hydroxide filter cake resulting from the treatment of wastewater originating from its electroplating operations. After evaluating the petition, EPA proposed, on August 21, 1992 to exclude POP's waste from the lists of hazardous waste under §§ 261.31 and 261.32 (see 57 FR 37921).

The Agency did not receive any public comments on the proposal and this rulemaking finalizes the proposed decision to grant POP's petition.

II. Disposition of Petition

A. POP Fasteners, Shelton, Connecticut

1. Proposed Exclusion

POP Fasteners, located in Shelton, Connecticut, petitioned the Agency to exclude from hazardous waste control its metal hydroxide filter cake resulting from the treatment of wastewaters originating from its electroplating operations, presently listed as EPA Hazardous Waste No. F006—"Wastewater treatment sludges from electroplating operations except from the following processes: (1) Sulfuric acid anodizing of aluminum; (2) tin plating on carbon steel; (3) zinc plating (segregated basis) on carbon steel; (4) aluminum or zinc-aluminum plating on carbon steel; (5) cleaning/stripping associated with tin, zinc and aluminum plating on carbon steel; and (6) chemical etching and milling of aluminum". The listed constituents of concern for EPA Hazardous Waste No. F006 waste are: Cadmium, hexavalent chromium, nickel and cyanide (complexed) (see Part 261, Appendix VII).

In support of its petition, POP submitted: (1) Detailed descriptions of its manufacturing and waste treatment processes, including schematic diagrams;[1] (2) a list of all raw materials and Material Safety Data Sheets (MSDSs) for all trade name products used in the manufacturing and waste treatment processes; (3) results from total constituent analyses for the eight Toxicity Characteristic (TC) metals listed in § 261.24 and nickel; (4) results from the Toxicity Characteristic Leaching Procedure (TCLP; as described in part 261, appendix II) analyses for the eight TC metals and nickel; (5) results from total constituent analyses for volatile and semi-volatile organic compounds and polychlorinated biphenyls; (6) results from total constituent analyses for total and reactive sulfide and cyanide for representative samples of the petitioned waste; (7) results from total oil and grease analyses on representative samples of the petitioned waste; and (8) test results and information regarding the hazardous characteristics of ignitability, corrosivity, and reactivity.

The Agency evaluated the information and analytical data provided by POP in support of its petition and determined that the hazardous constituents found in the petitioned waste would not pose a threat to human health and the environment. Specifically, the Agency used the modified EPA Composite Model for Landfills (EPACML) to predict the potential mobility of the inorganic hazardous constituents found in the petitioned waste, and used the EPACML/the Organic Leachate Model (OLM) to estimate the leachable portion of the organic contaminants in the petitioned waste.

Based on the evaluation, the Agency determined that the constituents in POP's petitioned waste would not leach and migrate at concentrations above the Agency's health-based levels used in delisting decision-making. See 57 *FR* 37921, August 21, 1992, for a detailed explanation of why EPA proposed to grant POP's petition for its metal hydroxide filter cake.

2. Response to Public Comments

The Agency did not receive any public comments on the proposal.

3. Final Agency Decision

For the reasons stated in the proposal, the Agency believes that POP's metal hydroxide filter cake should be excluded from hazardous waste control. The Agency, therefore, is granting a final exclusion to POP Fasteners, located in Shelton, Connecticut, for its

[1] POP has claimed portions of their manufacturing and treatment process descriptions as confidential business information (CBI). This information, therefore, is not available in the RCRA public docket for today's notice.

metal hydroxide filter cake, described in its petition as EPA Hazardous Waste No. F006.

This exclusion only applies to the processes and waste volume (a maximum of 300 cubic yards generated annually) covered by the original demonstration. The facility would require a new exclusion if either its manufacturing or treatment processes are significantly altered such that an adverse change in waste composition (*e.g.*, if levels of hazardous constituents increased significantly) or increase in waste volume occurred. Accordingly, the facility would need to file a new petition for the altered waste. The facility must treat waste generated either in excess of 300 cubic yards per year or from changed processes as hazardous until a new exclusion is granted.

Although management of the waste covered by this petition would be relieved from the Subtitle C jurisdiction upon final promulgation of an exclusion, the generator of a delisted waste must either treat, store, or dispose of the waste in an on-site facility, or ensure that the waste is delivered to an off-site storage, treatment, or disposal facility, either of which is permitted, licensed, or registered by a State to manage municipal or industrial solid waste. Alternatively, the delisted waste may be delivered to a facility that beneficially uses or reuses, or legitimately recycles or reclaims the waste, or treats the waste prior to such beneficial use, reuse, recycling, or reclamation.

III. Limited Effect of Federal Exclusion

The final exclusion being granted today is being issued under the Federal (RCRA) delisting program. States, however, are allowed to impose their own, non-RCRA regulatory requirements that are more stringent that EPA's, pursuant to Section 3009 of RCRA. These more stringent requirements may include a provision which prohibits a Federally-issued exclusion from taking effect in the State. Since a petitioner's waste may be regulated under a dual system (*i.e.*, both Federal (RCRA) and State (non-RCRA) programs), petitioners are urged to contact their State regulatory authority to determine the current status of their wastes under State law.

IV. Effective Date

This rule is effective on December 7, 1992. The Hazardous and Solid Waste Amendments of 1984 amended Section 3010 of RCRA to allow rules to become effective in less than six months when the regulated community does not need the six-month period to come into compliance. That is the case here because this rule reduces, rather than increases, the existing requirements for persons generating hazardous wastes. In light of the unnecessary hardship and expense that would be imposed on this petitioner by an effective date of six months after promulgation and the fact that a six-month deadline is not necessary to achieve the purpose of Section 3010, EPA believes that this rule should be effective immediately upon promulgation. These reasons also provide a basis for making this rule effective immediately, upon promulgation, under the Administrative Procedure Act, 5 U.S.C. 553(d).

V. Regulatory Impact

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. This rule to grant an exclusion is not major since its effect is to reduce the overall costs and economic impact of EPA's hazardous waste management regulations. This reduction is achieved by excluding waste generated at a specific facility from EPA's lists of hazardous wastes, thereby enabling the facility to treat its waste as non-hazardous. There is no additional economic impact, therefore, due to today's rule. This rule is not a major regulation, therefore no Regulatory Impact Analysis is required.

VI. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. 601–612, whenever an agency is required to publish a general notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis which describes the impact of the rule on small entities (*i.e.*, small businesses, small organizations, and small governmental jurisdictions). The Administrator or delegated representative may certify, however, that the rule will not have a significant economic impact on a substantial number of small entities.

This amendment will not have an adverse impact on small entities since its effect will be to reduce the overall costs of EPA's hazardous waste regulations and is limited to one facility. Accordingly, I hereby certify that this regulation will not have a significant economic impact on a substantial number of small entities. This regulation, therefore, does not require a regulatory flexibility analysis.

VII. Paperwork Reduction Act

Information collection and recordkeeping requirements associated with this final rule have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96–511, 44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2050–0053.

VIII. Lists of Subjects in 40 CFR Part 261

Hazardous waste, Recycling, Reporting and recordkeeping requirements.

Authority: Sec. 3001(f) RCRA, 42 U.S.C. 6921(f).

Dated: November 12, 1992.

Jeffery D. Denit,

Deputy Director, Office of Solid Waste.

For the reasons set out in the preamble, 40 CFR part 261 is amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, and 6938.

2. In Table 1 of appendix IX of part 261, add the following wastestream in alphabetical order by facility to read as follows:

Appendix IX to Part 261—Wastes Excluded Under §§ 260.20 and 260.22

TABLE 1.—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES

Facility	Address	Waste description
•	•	• • • • •
POP Fasteners	Shelton, Connecticut	Wastewater treatment sludge (EPA Hazardous Waste No. F006) generated from electroplating operations (at a maximum annual rate of 300 cubic yards) after December 7, 1992. In order to confirm that the characteristics of the waste do not change significantly, the facility must, on an annual basis, analyze a representative composite sample for the constituents listed in § 261.24 using the method specified therein. The annual analytical results, including quality control information, must be compiled, certified according to § 260.22(i)(12) of this chapter, maintained on site for a minimum of five years, and made available for inspection upon request by any employee or representative of EPA or the State of Connecticut. Failure to maintain the required records on site will be considered by EPA, at its discretion, sufficient basis to revoke the exclusion to the extent directed by EPA.
•	•	• • • • •

[FR Doc. 92–29451 Filed 12–4–92; 8:45 am]
BILLING CODE 6560–50–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405, 410, and 414

[BPD–494–IFC]

RIN 0938–AD65

Medicare Program; Payment for Durable Medical Equipment and Orthotic, and Prosthetic Devices

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule implements section 4062(b) of the Omnibus Budget Reconciliation Act of 1987 which specifies that payment under the Medicare program for durable medical equipment, orthotics, and prosthetics furnished on or after January 1, 1989 is limited to the lower of the actual charge for the equipment or the fee schedule established by the carrier. We are setting forth the methods for computing fee schedules for six classes of these items. We are also describing how the fee schedules are updated in subsequent years.

DATES: Effective Date: These final regulations are effective for items furnished on or after January 6, 1993.

Comment Date: Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on February 5 1993.

ADDRESSES: Mail written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–494–IFC, P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Ave., SW, Washington, DC 20201, or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

Due to staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD–494–IFC. Comments received timely will be available for public inspection as they are received, generally beginning approximately three weeks after publication of this document, in room 309–G of the Department's offices at 200 Independence Ave., SW, Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: 202–690–7890).

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FOR FURTHER INFORMATION CONTACT:
Sam Della Vecchia—Requirement of Physician Order, (410) 966–5395
Bernard Patashnik—All Other Issues, (410) 966–4495.

SUPPLEMENTARY INFORMATION:

I. Background

Originally, under the provisions of sections 1833 and 1842 of the Social Security Act (the Act), payment for most physician and other medical and health services furnished under Part B of the Medicare program (Supplementary Medical Insurance) was made on a reasonable charge basis through contractors known as carriers. Durable medical equipment (DME) came under these general carrier contract and payment benefit provisions until January 1, 1989.

Section 1842(b)(3) of the Act provides that when payment is made on a charge basis, the charge must be reasonable. In determining the reasonableness of a charge for Medicare purposes, carriers are required to consider the following factors:

- The actual billed charge for the services.
- The customary charge for similar services generally made by the physician or supplier for the service.
- The prevailing charge in the locality for similar services.
- In the case of medical services, supplies, and equipment that, in the judgment of the Secretary, do not vary widely in quality from one supplier to another, the lowest charge levels at which the services or supplies are widely and consistently available in the locality. In general, payment for the services is to be based on the lowest of these factors.

After adjustment for the annual deductible amount, Medicare pays 80 percent of the reasonable charge. The rules governing payment of reasonable charges for Medicare Part B services are currently set forth in 42 CFR part 405, subpart E (§§ 405.501 through 405.580).

Prior to the enactment of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203) on December 22, 1987, section 1889 of the Act had established specific payment rules concerning purchase or rental of new and used durable medical equipment (DME) under Medicare Part B. Section 1861(n) of the Act defines DME as follows:

> The term 'durable medical equipment' includes iron lungs, oxygen tents, hospital beds, and wheelchairs * * * used in the patient's home (including an institution used as his home other than an institution that meets the requirements of subsection (e)(1) of this section or section 1819(a)(1)) whether furnished on a rental basis or purchased;

(Sections 1861(e)(1) and 1819(a)(1) of the Act describe hospitals and skilled nursing facilities, respectively.)

Implementing regulations at § 405.514 set forth three methods of payment for DME: Lease-purchase, lump-sum payment for purchase, and rental charges. The regulations provide for the carrier to make a determination of which of these methods of payment to use, based, in general, on the item's cost and expected duration of use. (Section 1889 of the Act was repealed by section 4062(d)(5) of Pub. L. 100–203, and in this interim final rule we are eliminating the provisions in § 405.514.)

II. Summary of New Legislation

Section 4062(b) of Public Law 100–203, which added subsection 1834 to the Act, provides for a completely restructured payment methodology for DME and orthotic and prosthetic devices. Section 1834 of the Act, as amended by section 411(g)(1) of the Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100–360), section 608(d)(22)(A) of the Family Support Act of 1988 (Pub. L. 100–485), sections 6112 and 6140 of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239), and sections 4152 and 4153 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508), provides special payment rules for DME, prosthetics, and orthotics furnished on or after January 1, 1989.

More specifically, sections 1834(a)(1)(A) and (B) and section 1834(h)(1)(A) of the Act provide that payment for DME, prosthetics, and orthotics is equal to 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item. (Under sections 1832(a)(1), 1833(a)(1)(I), and 1833(b) of the Act, this payment amount is reduced by any applicable deductible.) For public home health agencies (HHAs) (or HHAs that serve a significant number of low income patients) that furnish the item free of charge or for a nominal charge, payment is equal to 80 percent of the fee schedule amount only. Section 1834(a)(1)(C) of the Act requires that the method of payment set forth in section 1834(a) of the Act applies to all items of DME covered under part B or under part A if supplied by an HHA. Section 1834(h)(1)(D) of the Act requires that the method of payment set forth in section 1834(h) of the Act applies to all prosthetic and orthotic devices covered under Part B or under Part A if supplied by an HHA.

A. Fee Schedule Methodology

Sections 1834 (a)(2) through (a)(5), 1834(a)(7), and 1834(h) of the Act set forth six separate classes of DME, orthotics, and prosthetics and describe how the fee schedule for each class is established. The six classes of items are: (1) Inexpensive and other routinely purchased DME; (2) items requiring frequent and substantial servicing; (3) customized items; (4) oxygen and oxygen equipment; (5) prosthetic and orthotic devices; and (6) capped rental items. Section 1834(a)(6) of the Act sets forth an additional class of items called "other covered items (other than DME)." Section 1834(a)(13) of the Act defines the term "covered items" for section 1834(a) of the Act. The definition restricts the term to DME.

The original purpose of section 1834(a)(6) of the Act was to establish the payment methodology for prosthetics and orthotics. However, this section was not deleted when section 1834(h) was added by section 4153 of Public Law 101–508. We cannot reconcile the conflict between these two provisions, and we cannot determine which items Congress intends for section 1834(a)(6) of the Act to address. Therefore, we are not implementing any rules associated with section 1834(a)(6) of the Act.

1. Inexpensive and Other Routinely Purchased DME

Section 1834(a)(2) of the Act provides the rules for payment for inexpensive and other routinely purchased DME; that is, items whose purchase price does not exceed $150, or items that the Secretary determines are acquired through purchase at least 75 percent of the time. Payment for those items is made on a rental basis or in a lump-sum amount for the purchase of the item based on the amount allowed by the fee schedule for purchase or rental. The total Medicare payments for rental and purchase of an item may not exceed the amount that would be paid for purchase only.

For inexpensive and other routinely purchased DME, the fee schedule amount for an item furnished in a carrier service area in 1989 and 1990 is equal to the local payment amount, which is the average reasonable charge in that area for the purchase or rental for the 12-month period ending on June 30, 1987, increased by the percentage increase in the consumer price index for all urban consumers (CPI–U) for the 6-month period ending with December 1987. For each subsequent year, the fee schedule amount is limited to the national limited payment amount adjusted by the covered item update (see below at section II.A.8).

2. Items Requiring Frequent and Substantial Servicing

Section 1834(a)(3) of the Act provides the rules for payment for items requiring frequent and substantial servicing; that is, items for which there must be frequent and substantial servicing in order to avoid risk to the patient's health. This section specifically mentions ventilators, aspirators, intermittent positive pressure breathing machines, and nebulizers. Medicare payment for these items is made on a monthly basis and only for the rental of the item.

For items or devices requiring frequent and substantial servicing, the fee schedule amount for an item or device furnished in a carrier service area in 1989 and 1990 is the local payment amount. The local payment amount is the average reasonable charge in the area for the rental of the item or device for the 12-month period ending with June 1987, increased by the percentage increase in the CPI–U for the 6-month period ending with December 1987. For each subsequent year, the fee is limited to the national limited payment amount adjusted by the covered item update.

3. Customized Items

Section 1834(a)(4) of the Act provides the rules for payment for certain customized items; that is, covered items that are uniquely constructed or substantially modified to meet the specific needs of an individual patient and for that reason cannot be grouped with similar items for purposes of payment under the Medicare program. A lump-sum payment, determined by the carrier, is made for these items. In addition, during the period of medical need the carrier must make lump-sum payments for the reasonable and necessary maintenance and servicing for parts and labor not covered by the supplier's or manufacturer's warranty.

4. Oxygen and Oxygen Equipment

Section 1834(a)(5) of the Act provides that payment for oxygen and oxygen equipment is made in a monthly payment amount with a volume

adjustment, plus a monthly payment add-on amount for portable oxygen equipment if used. The volume adjustment is calculated as follows:

- If the attending physician prescribes an oxygen flow rate of more than four liters of oxygen per minute, the payment amount is increased by 50 percent. If a flow rate of less than one liter per minute is prescribed, the payment amount is reduced by 50 percent.
- If a physician prescribes a flow rate of more than four liters of oxygen per minute and portable oxygen equipment is also used, section 1834(a)(5)(D) of the Act provides that the monthly payment amount is increased by the greater of the volume adjustment or the monthly payment add-on amount for portable oxygen equipment, but not both.

Section 1834(a)(9)(A) of the Act specifies how the separate monthly payment amounts for oxygen and oxygen equipment and portable oxygen equipment are calculated. Each carrier must compute a base local monthly payment rate for each item (that is, a rate for oxygen contents and stationary oxygen equipment and a rate for portable oxygen equipment). The carrier must compute a base local average monthly payment rate per beneficiary that equals the total reasonable charges for the item during the 12-month period ending December 31, 1986 divided by the total number of months beneficiaries used the equipment and supplies during the 12-month period for which payment was made.

The fee schedule amount for oxygen furnished in a carrier service area in 1989 and 1990 is the local average monthly payment rate, which is equal to 95 percent of the base local average monthly payment rate per beneficiary, increased by the percentage increase in the CPI-U during the 6-month period ending December 1987. Beginning January 1, 1991 and for each subsequent year, the fee schedule amounts are limited to the national limited payment amounts increased by the covered item update.

5. Prosthetics and Orthotics

Section 1834(h)(1) of the Act provides that payment for prosthetics and orthotics is made in a lump sum for the purchase of the item in the amount recognized under section 1834(h)(2) of the Act. Section 1834(h)(2)(A) of the Act requires each carrier to compute a base local purchase price for each item. The base local purchase price is equal to the average reasonable charge in the locality for the purchase of the item for the 12-month period ending with June 1987. Each carrier must then compute a local purchase price for each particular item, which, in 1989 through 1991, is equal to the base local purchase price, increased by the percentage increase in the CPI-U for the 6-month period ending with December 1987. In 1992 and 1993, the local purchase price is equal to the local purchase price for the previous year increased by the applicable percentage increase for the year. The applicable percentage increase is equal to the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.

In addition, section 1834(h)(2)(B) of the Act requires the Secretary to compute a regional purchase price for 1992 that is equal to the average (weighted by relative volume of all claims among carriers) of the local purchase prices for the carriers in the region. For each subsequent year, the regional purchase price is equal to the regional purchase price for the previous year increased by the percentage increase in the CPI-U for the 12-month period ending with June of the previous year.

Section 1834(h)(2)(C) of the Act provides that the amount recognized under this paragraph as the purchase price for each item is as follows:

- For items furnished in 1989 through 1991, the amount is equal to 100 percent of the local purchase price.
- For items furnished in 1992, the amount is equal to the sum of 75 percent of the local purchase price and 25 percent of the regional purchase price.
- For items furnished in 1993, the amount is equal to the sum of 50 percent of the local purchase price and 50 percent of the regional purchase price.
- For items furnished in 1994 or a subsequent year, the amount is equal to the regional purchase price.

Section 1834(h)(2)(D) of the Act sets forth limitations on the amount recognized as the purchase price for an item furnished. In 1992, the amount may not be more than 125 percent nor lower than 85 percent of the average purchase price recognized for all carrier service areas in the United States in that year. In each subsequent year, the amount may not be more than 120 percent nor lower than 90 percent of the average purchase price recognized for all carrier service areas in the United States in that year.

6. Capped Rental Items

Section 1834(a)(7) of the Act provides for payment for other items of DME (that is, capped rental items) not described in sections 1834(a) (2) through (6) of the Act. Section 1834(a)(7)(A) of the Act specifies that payment for these items is made on the basis of monthly rental payments during the period of medical need with a purchase option provided after 10 months of rental. The monthly payment amount is 10 percent of the purchase price for the first 3 months of rental and 7.5 percent of the purchase price for the remaining rental months. (See section III.F. of this preamble for a detailed discussion of how the purchase price for the item is determined under section 1834(a)(8) of the Act.) Rental payments cannot extend over a "period of continuous use," as defined under § 414.230, of longer than 15 months. (See 56 FR 50821 which defined the phrase "period of continuous use.") If the period of medical need is longer than 15 months, payment is made as follows:

- For the first 6-month period of medical need after the 15 months have elapsed, no additional payments will be made for rental or maintenance and servicing.
- For the first month of each succeeding 6-month period of medical need, for items identified by the Secretary, a maintenance and servicing payment may be made for parts and labor not covered by the supplier's or manufacturer's warranty. The amount recognized for each of these 6-month periods is the lower of a reasonable and necessary maintenance and servicing fee established by the Secretary, or 10 percent of the recognized purchase price.

Section 1834(a)(7)(A)(ii) of the Act specifies that suppliers of DME must give the beneficiary the option to purchase an electric wheelchair on a lump-sum basis at the time the item is furnished.

Section 1834(a)(7)(B) of the Act specifies that for 1989 and 1990, the rental amount established may not be more than 115 percent nor less than 85 percent of the prevailing charge established for the rental of the item in January 1987, increased by the percentage increase in the CPI-U for the 6-month period ending December 1987.

Section 1834(a)(7)(C) of the Act specifies that if an item of DME has been in continuous use by the patient, on either a rental or purchase basis, for the equipment's useful lifetime or the item is lost or irreparably damaged, the patient may elect to obtain a new piece of equipment and have payment made on a monthly basis for the rental of the replacement or as a lump-sum amount for the purchase of the item. The reasonable useful lifetime of an item of equipment is 5 years unless the Secretary determines that 5 years is inappropriate.

Section 1834(a)(8) of the Act specifies how the purchase price that is recognized for capped rental items is determined. Section 1834(a)(8)(A) of the Act requires each carrier to compute a base local purchase price equal to the average of the purchase prices on claims submitted on an assignment-related basis for the new items supplied during the 6-month period ending with December 1986. Each carrier must then compute a local purchase price for each particular item, which, in 1989 and 1990, is equal to the base local purchase price, increased by the percentage increase in the CPI-U for the 6-month period ending with December 1987.

Also in 1991, the updated base local purchase price for capped rental items is decreased by the percentage by which the average of the reasonable charges for claims paid for these items is lower than the average of the purchase prices submitted for these items during the final 9 months of 1988. For each subsequent year, the fee schedule amounts are equal to the national limited payment amounts increased by the covered item update.

7. Covered Item Update

Section 1834(a)(14) of the Act provides for a covered item update to the national limited payment amounts for 1991 and subsequent years. The covered item update, as defined under section 1834(a)(14)(B) of the Act, is equal to the percentage increase in the CPI–U for the 12-month period ending with June of the previous year. Section 1834(a)(14)(A) of the Act specifies that the covered item update for 1991 and 1992 is a reduction of 1 percentage point in the CPI–U.

8. National Limited Payment Amounts

Sections 1834(a) (2), (3), (8) and (9) of the Act provide for application of a national limited payment amount. The national limited payment amount is computed as follows:

- The 1991 national limited payment amount is equal to:

—100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts;

—The sum of 67 percent of the local payment amount plus 33 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average; or

—The sum of 67 percent of the local payment amount plus 33 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average.

- The 1992 national limited payment amount is equal to:

—100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts;

—The sum of 33 percent of the local payment amount plus 67 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average; or

—The sum of 33 percent of the local payment amount plus 67 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average.

- For 1993 and subsequent years, the national limited payment amount is equal to:

—100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor is less than 85 percent of the weighted average of all local payment amounts;

—100 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average; or

—85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average.

9. Exceptions and Adjustments

Section 1834(a)(10) of the Act provides for the following exceptions and adjustments:

- Section 1834(a)(10)(A) of the Act provides for exceptions to be made to the amounts recognized under this section to take into account the unique circumstances of covered items furnished in Alaska, Hawaii, or Puerto Rico.

- Section 1834(a)(10)(B) of the Act provides that, for covered items furnished on or after January 1, 1989 and before January 1, 1991, the Secretary is precluded from applying the inherent reasonableness provisions under § 405.502 to covered items and suppliers of such items.

- Section 1834(a)(10)(C) of the Act provides that, in order to permit an attending physician time to determine whether the purchase of a transcutaneous electrical nerve stimulator (TENS) is medically appropriate for a particular patient, the Secretary may determine an appropriate payment amount for the initial rental of the item for a period of not more than 2 months. If the item is subsequently purchased, the payment amount is determined using the methodology for inexpensive and other routinely purchased DME, discussed above.

10. Other Statutory Provisions

Section 1834(a)(11)(A) of the Act requires a supplier of a covered item for which rental payment is made under section 1834(a) of the Act to continue to supply the item without charge (other than a charge for the maintenance and servicing of the item) after rental payments may no longer be made. If a supplier knowingly and willfully violates the provisions discussed above, the Secretary may apply sanctions against the supplier under section 1842(j)(2) of the Act in the same manner such sanctions may apply with respect to a physician.

Section 1834(a)(11)(B) of the Act authorizes the Secretary to require, for specified covered items, that payment be made only if a physician has provided a written order to the supplier for the item before its delivery.

Section 1834(a)(12) of the Act permits the Secretary to designate one carrier for each region to process all claims within the region for covered items under section 1834(a) of the Act.

Section 1834(a)(13) of the Act defines the term "covered item" for purposes of section 1834(a) of the Act as durable medical equipment (as defined in section 1861(n) of the Act), including equipment described in section 1861(m)(5) of the Act.

Section 1834(h)(4) of the Act defines the term "covered item" for purposes of section 1834(h) of the Act as the following:

- Prosthetic devices (described in section 1861(s)(8) of the Act) but not including parenteral and enteral nutrition nutrients, supplies, and equipment; and

- Orthotics and prosthetics (described in section 1861(s)(9) of the Act) except for intraocular lenses or medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care) furnished by a home health agency under section 1861(m)(5) of the Act.

Section 1834(a)(1)(D) of the Act provides for a 15 percent reduction in payment amounts for payments computed under section 1834(a)(1)(B) of the Act for seat-lift chairs and TENS units furnished on or after April 1, 1990. Payment amounts for TENS units furnished on or after January 1, 1991 shall be reduced by an additional 15 percent. Effective January 1, 1991, section 1861(n) of the Act excludes seat-

lift chairs from the definition of DME but includes the seat-lift mechanism. We have not included any discussion of seat-lift chairs in this interim final rule with comment period but intend to conform the change in the statutory requirements for the coverage of seat-lift chairs in a separate rulemaking document.

III. Provisions of This Interim Final Rule

Section 1834 of the Act requires the establishment of fee schedules under Medicare Part B (and under Medicare Part A for an HHA) for payment of charges for covered DME, prosthetics, and orthotics. In general, payment is limited to the lower of the actual charge for the item or the fee schedule amount. The items are classified into the following six groups for purposes of determining the fee schedules and making payments:

- Inexpensive or routinely purchased DME.
- Items requiring frequent and substantial servicing.
- Certain customized items.
- Oxygen and oxygen equipment.
- Prosthetic and orthotic devices.
- Other DME (capped rental items).

Payment based on the fee schedules is effective with covered items furnished on or after January 1, 1989. In 1991 and in subsequent years, the fee schedules are adjusted to reflect changes in the level of the CPI–U. After adjustment for the annual deductible amount, Medicare pays 80 percent of the lower of the actual charge or the fee schedule amount. In addition, section 1834(a)(10)(B) of the Act provides that, for covered items furnished on or after January 1, 1991, the provisions of sections 1842(b) (8) and (9) of the Act, which involve adjustments for inherent reasonableness, will apply to the covered items and suppliers of such items.

In defining the area to use as the basis for computing payment rates, Congress uses several different terms (carrier service area, area, and locality) interchangeably. (See sections 1834(a)(2)(B), 1834(a)(8)(A)(i)(I), and 1834(a)(9)(A)(i) of the Act.) In the absence of Congressional direction, we intend to consider the use of each of these terms to mean the carrier service area for purposes of administering the fee schedule payment provisions. Therefore, the fee schedule amounts are determined on a carrier-specific basis using the current carrier service areas, except that if a carrier service area includes more than one entire State, then the fee schedule amounts will be determined on a single State basis. We note that in the Kansas City and Washington, DC metropolitan areas, which include portions of more than one State, but not more than one entire State, the entire carrier service area will be used in determining the fee schedule amounts. Also, due to the merging of the reasonable charge data base and screens in 1981 for the carrier service areas administered by Empire Blue Cross and Blue Shield and Group Health Incorporated, both of these carriers use uniform DME pricing. We see no need to revise the uniform pricing in these two New York carrier areas. Such revision would be inconsistent with the allowable charge data in effect prior to the fee schedule methodology. As such, the two carriers will continue to develop uniform DME pricing, the effect treating the two carrier services areas as one.

On November 6, 1991, we published a separate proposed rule (56 FR 56612) that would reduce to 4 or 5 the number of carriers that handle claims for DME, prosthetic and orthotic devices. When the proposed rule is made final and these new carriers begin processing claims, the fee schedule amounts will be determined on a single State basis.

Because the fee schedule amounts vary by carrier service area, we are not publishing those amounts in this document; rather, interested individuals or organizations may obtain information directly from the appropriate carrier about the fee schedule amounts that will apply to specific items from the appropriate carrier.

A. Inexpensive or Routinely Purchased DME

Under section 1834(a)(2) of the Act, inexpensive DME is defined as equipment whose purchase price does not exceed $150. Using the HCFA Common Procedure Coding System (HCPCS) codes, we complied a national list of items whose purchase prices do not exceed $150. To compile the list, we requested that each carrier submit purchase price information on all items of DME.

In the absence of a statutory directive that defines the period for determining which items are inexpensive, we selected the period July 1, 1986 through June 30, 1987. We selected this period because it is the same 12-month period required by section 1834(a)(2)(B)(i) of the Act for calculating the base fee schedule amount for inexpensive equipment.

We determined which items are to be included in the inexpensive category based on the national weighted mean submitted charge for purchase of the item. The national list of HCPCS codes for equipment determined to be inexpensive DME was furnished to carriers through an administrative instruction (Transmittal No. 1279, issued in November 1988), which added a new section 5102 to the Medicare Carriers Manual (HCFA Pub. 14–3). We are not including that list in this document as it requires periodic revision. We believe that publication in the **Federal Register** of the periodic revisions would be administratively burdensome and time-consuming.

If an item of equipment is included on the national list, we will continue to consider it an inexpensive item, for purposes of these provisions, even if, because of inflation, its average submitted charge exceeds $150 in a subsequent year. We do not believe that it was the intent of Congress that the effect of inflation on inexpensive items would change the original definition of those items. Had Congress intended, we believe it would have stated that intent and provided the methodology for recomputation.

Under section 1834(a)(2) of the Act, the Secretary determines that an item represents routinely purchased DME if it is acquired by purchase at least 75 percent of the time. We requested data from each carrier on purchase and rental information. We asked the carriers to identify which items of DME are purchased and which items of DME are rented and not subsequently purchased. In the absence of a statutory directive that defines the period for determining which items are routinely purchased, we selected the period July 1, 1986 through June 30, 1987 because it is the same 12-month period required by section 1834(a)(2)(B)(i) of the Act for calculating the base fee schedule amount for routinely purchased equipment. We then determined which items are to be included in the frequently purchased category based on whether the item was purchased 75 percent of the time on a national basis. The national list of HCPCS codes for equipment determined to represent routinely purchased DME was furnished to carriers through the implementing instructions.

Another alternative in the way we categorize inexpensive equipment is to use the supplier's submitted purchase price to determine whether an item is inexpensive. If the submitted purchase price, that is, the actual charge, is less than $150, the item would be considered inexpensive even if the item was in another category, such as capped-rental, frequent servicing, or oxygen equipment. We realize that this alternate methodology may create inconsistencies among carrier

jurisdictions and may not be consistent with the national limited payment amounts that go into effect in 1991. For example, a capped rental item in one jurisdiction may be considered inexpensive in an adjacent jurisdiction. For these reasons, we are interested in receiving comments regarding this alternate methodology.

Payment for inexpensive or routinely purchased DME is made for either rental or purchase of the equipment, but the total amount recognized for payment purposes for a particular item may not exceed the amount allowed for the item if purchased. Thus, for rental and purchase charges in total, we will pay no more than the lower of the actual charges or purchase fee schedule amounts (less any deductibles and coinsurance) for these items.

In calculating the average reasonable charge for determining payment for inexpensive and routinely purchased DME under section 1834(a)(2) of the Act, the carriers will calculate the weighted mean of the allowed charges for the items. We chose this calculation because the allowed charge is the carrier's determination of the reasonable charge for an item, and the weighted mean is the customary method of calculating an average.

The carriers calculate separate fee schedules for rental and for purchase of new and used equipment in the carrier service area. The carrier service area is defined as the entire area serviced by the carrier not to exceed the boundary of any State except for those carriers servicing the Kansas City and Washington, DC metropolitan areas. This methodology establishes fee schedules on the basis of a single locality per carrier except those servicing multiple States. (As noted above, on November 6, 1991, we published a separate proposed rule (56 FR 56612) that would reduce to 4 or 5 the number of carriers that handle claims for DME, prosthetic and orthotic devices. When the proposed rule is made final and these new carriers begin processing claims, the fee schedule amounts will be determined on a single State basis.) In the overwhelming majority of situations, the reasonable charge for used equipment is lower than the reasonable charge for new equipment. Using separate fee calculations for new and used equipment provides recognition of the difference in charges and eliminates any bias toward overpaying for used equipment or underpaying for new equipment that a combined fee calculation would cause.

Under the reasonable charge methodology in effect for DME prior to January 1, 1989, payment could be made on claims for maintenance and servicing of purchased items paid for under section 1834(a)(2) of the Act. However, as discussed below, section 1834(a)(4) of the Act, with regard to certain customized items, does provide for an amount for reasonable and necessary maintenance and servicing for parts and labor not covered by the supplier's or manufacturer's warranty. We believe that the inclusion of a payment provision in section 1834(a)(4) of the Act for maintenance and servicing of purchased equipment, despite the absence of a similar provision in section 1834(a)(2) of the Act, indicates that Congress recognized the need to maintain purchased items and authorized payment to meet that need. Therefore, for inexpensive and other routinely purchased items, we will make a separate lump-sum payment, on an as needed basis, for the reasonable and necessary maintenance and servicing not covered under warranty.

However, we will not make payment for maintenance and servicing of rented equipment in the inexpensive and other routinely purchased equipment category. We have historically never allowed separate payment for maintenance and servicing of rented equipment because title to and, thus, responsibility for the rented equipment remains with the supplier of the equipment. Rental payments made on a reasonable charge basis would have included the supplier's expenses for the provision of maintenance and servicing of the rented equipment. Because HCFA used historical charge data in calculating the rental fee schedule amounts, it has already included a reasonable amount for maintenance and servicing in the fee schedule. Therefore, no separate payment for maintenance and servicing of rented equipment is provided since such payment would represent duplicate payment for maintenance and servicing.

This rule will apply similarly to situations in which a beneficiary decides to continue renting equipment in this category beyond the purchase price limitation. Since ownership of the equipment remains with the supplier, maintenance and servicing of the equipment is also the supplier's responsibility.

As required by section 1834(2)(B)(i) of the Act, the average reasonable charges for inexpensive or routinely purchased DME, as determined for the 12-month period ending June 30, 1987, will be adjusted by the change in the level of the CPI–U for the 6-month period ending December 1987. These adjusted amounts are the fee schedule amounts effective for items furnished in 1989 and 1990. For subsequent years, the fee schedule amounts are equal to the national limited payment amounts adjusted by the covered item update.

Section 1834(a)(2)(C) of the Act provides for a covered item update for 1991 and subsequent years, and section 1834(a)(14) of the Act establishes the amount of the update. For 1991 and 1992, the covered item update is the CPI–U minus 1 percentage point. Beginning in 1993, the covered item update is equal to the percentage increase in the CPI–U for the 12-month period ending with June of the previous year.

Sections 1834(a) (2) and (3) of the Act provide for application of a national limited payment amount. Section 1834(a)(8) of the Act provides for application of a national limited purchase price and section 1834(a)(9) of the Act provides for application of a national limited monthly payment rate. Since the methodology for computing the payment amount, purchase price, and monthly payment rate is the same, for ease of reference, we are using only one term—national limited payment amount. Similarly, these sections also provide for computation of local payment amount, local purchase price, and local monthly payment rate. Again, for ease of reference, we are using local payment amount as equivalent to local purchase price and local monthly payment rate.

The national limited payment amount is computed as explained in section II.A.8 above.

B. Items Requiring Frequent and Substantial Servicing

Under section 1834(a)(3) of the Act, we make monthly payments for the rental of certain covered items that require frequent and substantial servicing in order to avoid risk to the patient's health. Section 1834(a)(3) of the Act specifies that these items include—

- Ventilators.
- Aspirators.
- Intermittent positive pressure breathing machines.
- Nebulizers.

In addition, officials representing the DME industry have recommended that we include continuous passive motion machines and continuous positive pressure breathing machines in this category of DME. Based on our review, we agree that both types of machines require frequent and substantial servicing in order to avoid risk to the patient's health. Therefore, we are including both of these items in this category.

Using the data for the period July 1, 1986 through June 30, 1987 (the base period prescribed under section 1834(a)(3)(B)(i) of the Act), the carriers use the same methodology for calculating and updating the fee schedule amounts as described above for rental in the inexpensive or routinely furnished DME category.

At this time, payment under these provisions for items requiring frequent and substantial servicing will be limited to those items listed above. However, we are specifically requesting public comments on other items that may require frequent and substantial servicing, and should be included in this payment category. It is our intention, based on administrative review, to add or delete items from this list and publish those changes in the Medicare Carriers Manual. We believe that this administrative approach for making changes to the list would be the most expeditious way of responding to technological changes.

Under the reasonable charge methodology in effect prior to January 1, 1989, payment was available for purchased, as well as rented, items requiring frequent and substantial servicing. It was our initial judgment that Congress did not intend to preclude payment for the purchase of these items. The initial carrier manual implementing instructions provided for payments for such purchases and for subsequent maintenance and servicing for items furnished on or after January 1, 1989. However, based upon further study of the statute, we now believe that the statute does not provide for continued purchase; nor does it authorize payment for maintenance and servicing of such equipment. Accordingly, for items furnished on or after June 1, 1989, payment will be only for rental items with no provision for maintenance, servicing, or replacement. We revised the Medicare Carriers Manual instructions (See Transmittal No. 1310, issued in June 1989.) to implement this revised policy.

C. Certain Customized Items

Under section 1834(a)(4) of the Act, we make lump-sum payments for certain items that are uniquely constructed or substantially modified to meet the specific needs of an individual patient and for that reason cannot be grouped with similar items for purposes of Medicare payment. Payments are based on the carrier's individual consideration of the item and include a separate lump-sum payment for the reasonable and necessary maintenance and service for parts and labor not covered by the supplier's or manufacturer's warranty, when necessary during the period of medical need.

Section 4152(c)(4)(B)(i) of Pub. L. 101–508 amended section 1834(a)(4) of the Act to define which wheelchairs are to be treated as customized items. The statutory definition was to take effect on January 1, 1992 unless the Secretary developed specific criteria before that date for the treatment of wheelchairs as customized items in which case the statutory definition would not become effective. On December 20, 1991, the Secretary's definition of all customized items, including customized wheelchairs, was published in an interim final rule with comment period in the **Federal Register** (56 FR 65995). This definition is set forth at § 414.224(a) and supersedes the definition in section 1834(a)(4) of the Act.

D. Oxygen and Oxygen Equipment

Section 1834(a)(5) of the Act provides for a monthly payment amount per beneficiary for oxygen and oxygen equipment. An add-on payment is made when portable oxygen equipment is used in addition to stationary equipment. As described in section 1834(a)(9) of the Act, separate monthly payment amounts are set for oxygen contents and stationary oxygen equipment and for portable oxygen equipment. For oxygen contents and stationary oxygen equipment, the carrier computes a payment rate on the basis of a base local average monthly payment rate per beneficiary that is equal to the total reasonable charges for the oxygen contents and stationary oxygen equipment for the 12-month period ending December 1986 divided by the total number of months for all beneficiaries receiving those items for the same period. To determine the fee schedule for 1989 and 1990, the base amount is multiplied by 95 percent and then is adjusted by the change in the CPI–U for the 6-month period ending December 1987.

For portable oxygen equipment, the carrier computes a payment rate on the basis of a base local average monthly payment rate that is equal to the total reasonable charges for portable equipment for the 12-month period ending December 1986 divided by the total number of months for all beneficiaries receiving that item for the same period. Oxygen contents are not included. To determine the fee schedule for 1989 and 1990, the base amount is multiplied by 95 percent and then adjusted by the change in the CPI–U for the 6-month period ending December 1987. We have decided to exclude purchased equipment from the payment computation since purchased equipment will not be paid for under the fee schedule methodology.

Since there will be some purchased systems in use for which there will be only a requirement for oxygen contents, we are requiring carriers to compute a "contents only" monthly fee schedule amount using the same methodology as above, except that the calculations will be based on oxygen contents (gas or liquid) exclusive of any equipment charges. For purchased oxygen systems there will be no payment for equipment. The "contents only" monthly fee schedule amount will be paid for previously purchased liquid or gaseous systems. No payment will be made for previously purchased concentrators. Similarly, there will also be a portable contents only fee schedule amount established and paid when a portable system is either owned or rented and a concentrator is owned or no stationary system of any type is used. The portable contents only fee is computed by dividing the allowed charges for portable oxygen by the number of months of all beneficiaries receiving the item during the period. Payment for oxygen use is also affected by the oxygen flow rate. If the attending physician prescribes an oxygen flow rate exceeding four liters per minute, the payment amount for the oxygen contents and stationary oxygen equipment, subject to a limit for those cases in which portable equipment is also used, is increased by 50 percent. If the prescribed oxygen flow rate is less than one liter per minute, the fee schedule amount for the item is decreased by 50 percent. Under section 1834(a)(5) of the Act, for those cases in which portable equipment is used and the oxygen flow rate exceeds four liters per minute, the increase to the fee schedule for oxygen and oxygen equipment is limited to the higher of the fee schedule for portable oxygen equipment or the 50 percent increase for the flow rate adjustment.

Section 1834 of the Act is silent regarding volume adjustments when the prescribed oxygen liter flow varies according to the circumstances of the patient. Therefore, we intend to apply the volume adjustment in the following manner. If the prescribed oxygen liter flow rate is different for the stationary oxygen equipment than it is for the portable oxygen equipment, we believe that, for ease of administration, carriers should use the prescribed amount for stationary equipment because, in terms of time, it is the most frequently used equipment. Carriers would have no credible way of determining the

proportion of time patients used their stationary equipment in relation to their portable equipment. Similarly, we believe the payment amount should be based on the prescribed flow rate for patients at rest, rather than the exercise rate; again, because the rest flow rate occurs more frequently. Carriers would have no credible way of determining the proportion patients used their portable equipment while exercising rather than using stationary equipment while at rest. We believe that use of portable equipment in relation to stationary equipment is so infrequent as to be inconsequential, and it would not be worth the administrative costs required for carriers to calculate the differentials. If the prescribed oxygen liter flow is different for day and night use, we believe that it is more equitable for the carrier to apply an average of the two rates since the periods of use for day and night are more nearly equal.

For 1989 and 1990, the base monthly payment amount for oxygen and oxygen equipment is 100 percent of the local average monthly payment rate. For 1991 and subsequent years, the local average monthly payment amount is adjusted by the covered item update and application of the national limited payment amount as described above for rental in the inexpensive or routinely furnished DME category.

E. Prosthetic and Orthotic Devices

Section 1834(h) of the Act provides that payment be made on a lump-sum basis for prosthetic and orthotic devices and sets forth the specific payment provisions applicable to this category of covered items. Under section 1834(h)(2)(A) of the Act, the carrier computes a base local purchase price equal to the average reasonable charge in the carrier service area for each of the other covered items that are furnished during the period July 1, 1986 through June 30, 1987, and adjusts the price by the change in the level of the CPI–U for the 6-month period ending December 1987.

The carrier determines the average reasonable charge in the area for the purchase of the item, based on the mean of the carrier's reasonable charges for the item. In determining the payment for 1991 through 1993, the carrier updates the local purchase price for the item for the preceding year by the applicable percentage increase. For 1991, the applicable percentage increase provided by section 1834(h)(4) of the Act is 0 percent. For 1992 and 1993, the applicable percentage increase is equal to the change in the level of the CPI–U for the 12-month period ending with June of the previous year. For 1992, we will also compute a regional purchase price equal to the average, weighted by the relative volume of all claims, of the local purchase prices for the carriers in the region. For each subsequent year, the regional purchase price is increased by the applicable percentage increase. For weighting, we intend to use the total claims volume for each carrier in each region. We considered the possibility that the statutory requirement to weight by the relative volume of all claims may have been intended to mean the relative volume of claims on an item-by-item basis. We rejected the item-by-item approach because we believe the chance of a gross error in data collection of frequency counts is significantly less for a single aggregate count in contrast to the chances for error in computing hundreds of frequency counts. For items that are not commonly billed, even modest errors in frequency counts could create unfair weights. For 1994 onward, we will update the regional purchase price by the change in the level of the CPI–U for the 12-month period ending with June of the previous year.

For 1989 through 1991, the fee schedule amount for prosthetic and orthotic devices is 100 percent of the local purchase price. For 1992, the fee schedule amount for the item is equal to 75 percent of the local purchase price and 25 percent of the regional purchase price. For 1993, the fee schedule amount for the item is equal to 50 percent of the local purchase price and 50 percent of the regional purchase price. For 1994 and subsequent years, the fee schedule amount for the item is 100 percent of the regional purchase price.

The fee schedule amount for prosthetic and orthotic devices is the amount recognized as the purchase price. However, for 1992, the fee schedule amount for the item may not be more than 125 percent, nor lower than 85 percent, of the average of the amount recognized as the purchase price for the item for all carrier service areas in the United States. For 1993 and subsequent years, the fee schedule amount for the item may not be more than 120 percent, nor lower than 90 percent, of the average of the amounts recognized as the purchase price for the item for all carrier service areas in the United States.

F. Other DME (Capped Rental Items)

Under section 1834(a)(7) of the Act, payment is made on a monthly basis for the rental of other items of DME that are not paid for under the other five classes of items set forth in sections 1834(a)(2) through (5) and section 1834(h) of the Act. For capped rental DME items furnished on or after January 1, 1991, suppliers must offer a purchase option of beneficiaries during the 10th continuous rental month; and for power-driven wheelchairs, a purchase option must also be made at the time the equipment is initially furnished. If the beneficiary does not exercise the purchase option, payment for the equipment may not exceed a period of continuous use of longer than 15 months. If the beneficiary elects the purchase option in the 10th month, payment may not exceed a period of continuous use of longer than 13 months. On the first day after 13 continuous rental months have been paid, the supplier must transfer title to the equipment to the beneficiary. In the case of power-driven wheelchairs, if the beneficiary elects the purchase option at the time the equipment is initially furnished, payment is made on a lump-sum basis.

The monthly payment amount for rental equipment may not exceed 10 percent of the purchase price for the first 3 months of rental and 7.5 percent of the purchase price for the remaining rental months. As required under section 1834(a)(8)(A)(i)(II) of the Act, the carrier computes a base local purchase price equal to the average of the purchase prices on the claims submitted on an assignment-related basis for the unused items supplied during the period July 1, 1986 through December 31, 1986.

The House Committee Report indicates that, "In calculating the purchase price for this category of DME, the carriers would use the arithmetic mean of the submitted purchase prices * * * indicated on claims that were submitted by suppliers on an assigned basis for items furnished during the period of July through December 1986." (See H.R. Rep. No. 391, 100th Cong., 1st Sess. 395 (1987).) Thus, in keeping with congressional intent, payment will be based on submitted charges for 1989 and 1990.

The House Committee Report also states that: "The Committee also expects the carriers to use the information about purchase prices that was submitted with claims, even though the item was reimbursed on a rental basis. (Current regulations implementing the rent/purchase rules require that both rental charges and purchase charges be submitted on a bill in order for the carrier to make a rent/purchase decision.)" (H.R. Rep. No. 391, 100th Cong., 1st Sess. 395–396 (1987).) Therefore, the purchase prices used to calculate the payment includes the purchase prices submitted on rental claims (in which the purchase

information was submitted as a result of the rent/purchase provision). This would increase the base for determining the average purchase price. We do not believe, however, that each rental month should be included in the base because to do so would be an unwarranted duplication of the same information. Rather, the purchase price used to make the rent/purchase decision will be counted once in determining the purchase price regardless of the length of the rental episode. The carrier determines the local purchase price for 1989 and 1990 by adjusting the base local purchase price by the change in the CPI–U for the 6-month period ending December 1987.

For 1989 and 1990, the amount recognized as the purchase price for other DME is 100 percent of the local purchase price. However, in 1989 and 1990, the fee may be no more than 115 percent and no less than 85 percent of the prevailing charge, as determined under § 405.504, for rental of the item in January 1987, adjusted for the change in the level of the CPI–U for the 6-month period ending December 1987.

Section 1834(a)(8)(A)(ii)(II) of the Act requires that during calendar year 1991 the local purchase price, increased by the covered item update for 1991, be decreased by the percentage by which the average of the reasonable charges for claims paid for all capped rental items in the carrier service area is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988. For years after 1991, the local purchase price is adjusted by the covered item update.

In addition, for 1991 and subsequent years, the local purchase price is limited by application of the national limited payment amount as described above for rental in the inexpensive or routinely furnished DME category.

Section 1834(a)(7)(A) of the Act requires that the Secretary determine the meaning of the term "continuous use" as it is used in defining the 15-month and 13-month periods for which we make payment for capped rental DME items. On October 9, 1991, we published an interim final rule with comment period in the Federal Register (56 FR 50821) that provides, at § 414.230, that a period of continuous use begins with the first month of medical need and continues until the patient's medical need for a particular item of equipment ceases.

The statute is unclear with regard to the responsibility of suppliers for continued provision and maintenance of items after 15 months rental in a case in which there has been a change in suppliers during the initial 15-month rental period. Section 1834(a)(11)(A) of the Act, states that, "* * * a supplier of a covered item for which payment is made under this subsection * * * shall continue to supply the item without charge * * *," when the 15-month rental period ends. If the beneficiary changes suppliers during or after the 15-month rental period, that change would not result in a new rental episode. For example, if the beneficiary changed suppliers after the 8th month of the rental period, the new supplier would be entitled to the monthly rental fee for 7 additional months. The supplier that has provided the item in the 15th month of the rental period would be responsible for supplying the equipment and for maintenance and servicing after the 15-month period.

As an alternative position, we considered requiring the supplier that had furnished the item for the longest portion of the rental period to be responsible for the period of continuous use of the equipment after the 15-month period expired. However, we are concerned about the possible inconveniences to the beneficiary and the initial supplier; for example, the longest term supplier may be located some distance from the beneficiary's residence at the end of the 15-month continuous use period. In addition, we do not believe it is appropriate to require a supplier to service equipment that it did not furnish and with which it may not be familiar.

We also considered requiring the last supplier of an item to be responsible for a period of continuous use after the 15-month period but only if the supplier furnished the item for 3 consecutive months. However, based on our review of information and advice received from the DME industry, we are rejecting this option because of the inconveniences, similar to those discussed in the option set forth above, that could occur. We specifically request comments on this provision.

Under our regulations in effect prior to January 1, 1989, beneficiaries had the option of purchasing or renting DME that is covered under the provisions of sections 1834(a) (3), (5) and (7) of the Act (items requiring frequent and substantial servicing, oxygen equipment and capped rental items). Under initial instructions implementing the new DME fee schedules, we provided for the rental or purchase of these items.

While we thought that it was in the beneficiary's interest to allow them to purchase these items, after further consideration, we no longer believe that the statute provides authority for us to continue the purchase option for items requiring frequent and substantial servicing and for oxygen. Accordingly, for these items furnished on or after June 1, 1989, payment is made only for rented items (Transmittal No. 1310, issued June 1989). For items furnished prior to that date, we will pay for the purchase of these items as discussed in our original implementing instructions.

For capped rental items, section 4152(c)(2) of Pub. L. 101–508 revised the payment methodology to allow purchase in accordance with a specified schedule. Thus, beginning in 1991, beneficiaries are given a choice in the 10th month of rental as to whether they want to purchase these items, or for power-driven wheelchairs, in the first month.

After the 15-month period of continuous use has expired, no payment will be made for maintenance and servicing of the item during the succeeding 6-month period of medical need. Current Medicare instructions (section 2100.4 of the Medicare Carriers Manual) consider maintenance and servicing as interchangeable terms and repairs as a different item. We are, therefore, specifically defining "servicing", for purposes of the provisions of section 1834(a) of the Act, to include any repair.

During the first month of each succeeding 6-month period, a service and maintenance payment may be made for each item in the capped rental category not covered under any supplier or manufacturer warranty. The carrier must establish a reasonable fee or fees for maintenance and servicing for each identified item. However, in no case may the fee exceed 10 percent of the purchase price. The reasonable fee for maintenance and service is the only charge provided for after the 15-month period of rental. A reasonable and necessary payment may be made for capped rental items that are purchased under the purchase option provision.

If the beneficiary's medical necessity is interrupted after the 15-month period, the rules governing continuous medical need, discussed above, will also apply. That is, the beneficiary's period of continuous use after the initial 15-month period could be interrupted occasionally by various factors (such as hospitalization) without being terminated. However, claims for equipment that are submitted after the 15-month cap has been reached, and which purport to be for a new period of medical necessity, will be subjected to an intense carrier medical review.

Effective January 1, 1991, if a capped rental item of equipment has been in continuous use by a beneficiary on either a rental or purchase basis for the reasonable useful lifetime of the item,

or, if the equipment is lost or irreparably damaged, the beneficiary may elect to obtain payment for a replacement for the item. We will measure the reasonable useful lifetime of capped rental equipment beginning on the date the equipment is delivered to the beneficiary. We will not attempt to determine the actual age of the equipment. It would be infeasible to review the prior rental history of individual items of equipment; and, there are no payment distinctions based on age. The minimum length of a useful lifetime for capped rental equipment is 5 years, unless we determine otherwise.

Should the beneficiary elect to have payment made for a replacement item, payment is made on a rental or purchase basis. If the original equipment was rented, payment for the replacement is made on a rental basis using the methodology for capped rental equipment. If, however, the original equipment was purchased, payment for the replacement is made on a lump sum purchase basis.

Section 1834(a)(7) of the Act does not define the local area to be used for determining the fee for these items. We are defining the local area as the carrier service area. This would be consistent with the definition of local area used in sections 1834(a) (2) and (3) of the Act.

G. Other Provisions

1. Exceptions for Certain HHAs

Sections 1834(a)(1)(B)(ii) and 1834(h)(1)(C) of the Act provide an exception to the payment provisions for items furnished by public HHAs and HHAs with a significant portion of low-income patients. Those HHAs, as defined in § 413.13(a), will not be paid on the lesser of the actual charge or the fee schedule amount but solely on the basis of the fee schedules described under sections 1834(a) (2) through (5), 1834(a)(7), and 1834(h) of the Act.

2. Exceptions for Alaska, Hawaii, and Puerto Rico

Under section 1834(a)(10) of the Act, an exception to the usual payment amounts for DME and prosthetic and orthotic devices is to be recognized for covered items furnished in Alaska, Hawaii, and Puerto Rico. We believe this provision was intended to provide relief to these areas from the national limited payment amounts and regional rates.

3. Inherent Reasonableness Determinations

Section 1834(a)(10)(B) of the Act authorizes the Secretary of apply the provisions of section 1842(b) of the Act regarding inherent reasonableness determinations to payment for covered DME, prosthetics, and orthotics furnished on or after January 1, 1991. Applicable regulations are located in § 405.502(g). We have instructed carriers through a manual instruction (section 5102 of the Medicare Carriers Manual) not to apply this authority until 1991.

4. Transcutaneous Electrical Nerve Stimulator (TENS)

Under section 1834(a)(10)(C) of the Act, in order to permit an attending physician time to determine whether the purchase of TENS is medically appropriate for a particular patient, the Secretary may determine an appropriate payment amount for the initial rental of such item for a period of not more than 2 months. We also believe that an appropriate payment amount for TENS should be limited to 10 percent of the purchase price per month. Payment for purchase will be determined in the same manner as inexpensive or frequently purchased items of DME as provided under section 1834(a)(2) of the Act (see section III.A. above).

In this interim final rule, we are adding paragraph (f) under § 410.38, "Durable Medical Equipment: Scope and Conditions," to specify that Medicare Part B pays for TENS as a DME item. We believe that Congress clearly intends that TENS be treated as DME, since section 1834(a) of the Act, which is entitled "Payment for Durable Medical Equipment," explicitly provides for TENS payment at subsections 1834(a)(1)(D), (a)(10)(C) and (a)(15)(A) of the Act.

5. Improper Billing

Under section 1834(a)(11)(A) of the Act, a supplier of a covered item for which payment is made under section 1834(a) of the Act, and which is furnished on a rental basis, is required to continue to supply the item without charge (other than a charge for the maintenance and servicing of the item) after rental payments are discontinued. That is, suppliers are prohibited from charging for equipment intended for use by the beneficiary after the 15-month period of rental payment has ended. If a supplier knowingly and willfully violates this provision (that is, makes a prohibited charge), the Secretary may apply sanctions under section 1842(j)(2) of the Act.

We believe that the use of sanctions indicates Congress' fundamental concern that no charge for equipment should be made after 15 months of rental payments have been made. Therefore, we are interpreting this provision broadly. If a supplier makes any charge to any person or entity for an item that is used by a beneficiary (including renting equipment to family members for use by the beneficiary) after 15 months of rental payments have been made, the supplier will be subject to sanctions.

6. Requirement of Physician Order

Under section 1834(a)(11)(B) of the Act, the Secretary may require for specified items that payment will be made only if the physician has communicated a written order for the item to the supplier prior to delivery of the item.

In general, we believe that it is unnecessary to require evidence that a written physician order was received by the supplier prior to delivery of most items. However, we have been made aware that certain types of expensive DME and prosthetic devices are being advertised as "Medicare approved" and then sold to beneficiaries without a physician's prescription. The beneficiary expects that Medicare will pay for them. But when the contractor reviews the beneficiary's claim for the item in light of the beneficiary's medical condition, the contractor frequently determines that Medicare payment is inappropriate. When this situation occurs, the beneficiary is liable for paying for the item.

We believe that, using the Secretary's authority under section 1834(a)(11)(B) of the Act, these incidents can be reduced by HCFA requiring a qualified physician, familiar with the beneficiary's condition, to attest to the beneficiary's need for certain types of equipment prior to its delivery. Therefore, we are requiring a written physician order before delivery of the following items:

- Seat-lift mechanism.
- Power-operated vehicles used as wheelchairs.
- Decubitus care equipment, including mattresses and cushions for controlling decubitus ulcers.
- TENS.
- Other items as determined by HCFA through carrier instructions or as determined by Medicare carriers.

We believe requiring that a written physician order be received by the supplier before delivery of the item will provide beneficiaries reasonable assurance that the purchased items are covered and reimbursable under Medicare. We are revising §§ 410.36 and 410.38 to implement these provisions. In addition, we are revising an incorrect statutory citation in § 410.38(b).

7. Power-operated vehicles used as wheelchairs

Section 60–5 of the Coverage Issues Manual (HCFA Pub. 6) includes a long-standing requirement that, for power-operated vehicles (POVs) to be covered by Medicare, a specialist in physical medicine, orthopedic surgery, neurology, or rheumatology must provide an evaluation of the patient's medical and physical condition and a prescription for the vehicle to assure that the patient requires the vehicle and is capable of using it safely. We are revising § 410.38 to include this requirement. This requirement is consistent with section 1861(n) of the Act, which specifies that POVs must be determined to be necessary on the basis of the individual's medical and physical condition and must meet any safety requirements prescribed by the Secretary.

We believe that the involvement of a specialist in physical medicine, orthopedic surgery, neurology, or rheumatology is important to ensure that a covered POV is medically warranted and the person for whom it is prescribed has the ability to operate it safely and effectively. There is considerable danger associated with the use of a powered vehicle for many patients with the types of impairments that necessitate the use of a powered vehicle. Considering the risks that are involved, we believe an evaluation by one of these specialists is the best means of ensuring that a power-operated vehicle is medically appropriate. Specialists in these fields are the best trained to evaluate patients whose medical needs may be met by POVs.

8. Regional Carriers

Under section 1834(a)(12) of the Act, the Secretary may designate a single carrier for each region to process all claims in the region. A separate notice of proposed rulemaking was published in the **Federal Register** (56 FR 56612) on November 6, 1991 that would provide for the designation of regional carriers.

9. Transitional Payments Occurring During 13-Month or 15-Month Period of Continuous Use

The following transition rules apply for rental items of DME for which payment is made under section 1834(a)(7) of the Act, effective January 1, 1989. For purposes of calculating the 15-month rental period, the period begins with the first month of continuous rental, even if that period began prior to January 1, 1989. For example, if the rental period began on July 1, 1988, the carrier will use this date as the first month of rental. Likewise, for purposes of calculating the 10-month purchase option, the period also begins with the first month of continuous rental without regard to when that period started. For example, if the period began in August 1990, the 10-month purchase option must be offered to the beneficiary in May 1991, the 10th month of continuous rental. We believe that the statutory intent is to limit total rental payments to payment for 15 months, or for 13 months if the beneficiary elects the purchase option. In the example above, if we were to begin calculating the 15-month period on January 1, 1989 instead of the first month of rental, rental payments would be incurred for an additional 6 months beyond the 15-month limit.

If a beneficiary has reached (on a date of service prior to January 1989) the purchase price limitation on a rental claim, no further rental or purchase payments will be made. However, for capped rental items previously rented that have reached the purchase cap under the rent/purchase rules (but were not actually purchased), we will make payment on claims for maintenance and servicing fees effective July 1, 1989.

The following transition rules apply to items that require frequent and substantial servicing or capped rental items that were purchased prior to January 1, 1989:

- If a beneficiary purchased the equipment prior to January 1989, we would pay the reasonable charges for maintenance and servicing on a lump-sum, as needed, basis.
- If a beneficiary purchased the equipment even though the carrier determined that rental was more economical under the rent/purchase guidelines in the Medicare Carriers Manual, or if the beneficiary made an approved purchase on an installment plan, the carrier would make payment on an installment basis until the purchase price was reached or medical necessity ended. If the purchase price for items that require frequent and substantial servicing or capped rental items was not reached by January 1, 1989, the carrier would continue making payments on an installment basis but at the monthly rental fee schedule amount until the actual purchase charge is reached, the purchase fee schedule amount computed in accordance with our administrative instructions in effect prior to June 1, 1989 is reached, or medical necessity ends, whichever occurs first. The limitation on total payments to 15-months rental does not apply.

The following transition rules apply to items that require frequent and substantial servicing or capped rental items that were purchased between January 1, 1989 and June 1, 1989 (the effective date when payment for purchase of these items is prohibited):

- For equipment purchased during this period in either category, we would pay the reasonable charges for maintenance and servicing on a lump-sum, as-needed, basis.
- For equipment purchased during this period in either category, we would pay monthly installments equivalent to the rental fee schedule amounts until the actual purchase charge is reached, the purchase fee schedule amount computed in accordance with our administrative instructions in effect prior to June 1, 1989 is reached, or medical necessity ends, whichever occurs first. Payment may be made for purchase even if the purchase was preceded by a period of rental. However, total payments for rental plus purchase of capped rental items may not exceed the amount that would have been paid had the equipment been continuously rented for 15 months.

The following transition rules apply to oxygen equipment purchased prior to June 1, 1989:

- For oxygen equipment purchased prior to June 1, 1989, we would pay the reasonable charges for maintenance and servicing on a lump-sum, as-needed, basis.
- For oxygen equipment purchased prior to June 1, 1989, even though the carrier determined that rental was more economical under the rent purchase guidelines in the Medicare Carriers Manual, or if the beneficiary made an approved purchase on an installment plan, the carrier made payment on an installment basis until the purchase price was reached or medical necessity ended. If the purchase price has not been reached by June 1, 1989, we would continue paying on an installment basis but at the monthly rental fee schedule amount until the purchase price is reached or the medical necessity ends, whichever occurs first.

10. Fee Schedule Amounts for Seat-Lift Chairs and TENS

The 1990 fee schedule amounts for seat-lift chairs and for TENS furnished on or after April 1, 1990 are reduced by 15 percent. The 1991 fee schedule amounts for TENS furnished on or after January 1, 1991 are reduced by an additional 15 percent.

11. Replacement of Equipment

Although section 1834(a)(7)(C) of the Act provides for the replacement of

capped rental DME if the useful lifetime of the equipment has been reached, we believe that this provision also should extend to other types of purchased DME and prosthetic and orthotic devices. We anticipate establishing the useful lifetime of all purchased DME and prosthetic and orthotic devices and limiting repurchase to this useful life. At this time, we specifically solicit comments regarding the useful life of all purchased DME and prosthetic and orthotic devices subject to the fee schedule methodology. Such comments will be used in establishing program instructions concerning the reasonable useful lifetime of equipment.

IV. Changes to the Regulations

As noted in section I above, we are deleting the regulations at § 405.514 that deal with payment for DME under former section 1889 of the Act, which was repealed by section 4062(d)(5) of Pub. L. 100–203. We are implementing the new payment provisions in this interim final rule with comment period through regulations located in subpart B (Medical and Other Health Services) of part 410 (Supplementary Medical Insurance (SMI) Benefits), and subpart D (Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices) of 42 CFR part 414 (Payment for Part B Medical and Other Health Services). We intend to issue a separate final rule to move the other sections on reasonable charges currently located in subpart E of part 405 (that is, §§ 405.501 through 405.515 and §§ 405.541 through 405.544) to part 414.

V. Regulatory Impact Statement

A. Executive Order 12291

Executive Order 12291 (E.O. 12291) requires us to prepare and publish a regulatory impact analysis for any proposed rule that meets one of the E.O. 12291 criteria for a "major rule"; that is, that would be likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

B. Regulatory Flexibility Act.

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a rule would not have a significant economic impact on a substantial number of small entities. Because the scope of this interim final rule is so broad in its application, it is difficult to characterize accurately the entities that will be affected by this rule. We believe that most manufacturers and suppliers of DME and orthotic and prosthetic devices fall under the definition of a small entity as used in the RFA. Some manufacturers and suppliers, however, clearly have substantial regional or national sales, and do not, therefore, meet the definition of small entity.

Based on estimates of the total market for DME and prosthetic and orthotic devices, we believe this interim final rule will not have a significant impact on a substantial number of small entities. The overall sales in 1990 for DME, vision, hearing, orthotic, and prosthetic devices equalled $12.1 billion. As discussed below in section V. D. 1. of this preamble, we project that the budgetary impact of this regulation on most manufacturers and suppliers will be small. Thus, the Secretary certifies that this interim final rule will not have a significant impact on a substantial number of small entities.

C. Small Rural Hospitals

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a final rule may have a significant impact on the operations of a substantial number of small rural hospitals. The analysis must conform to section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that has fewer than 100 beds and is located outside a Metropolitan Statistical Area.

It is possible that hospitals manufacture certain customized items of DME, orthotics or prosthetics as well as supply items of DME. When hospitals submit bills for these items, however, they do so as a supplier and not as a hospital. Because we maintain separate data bases for suppliers and hospitals, we cannot identify which hospitals are also supplying DME. Thus, we cannot determine whether this rule will have a significant impact on a substantial number of small rural hospitals. We invite commenters to submit any information or data that can help us determine whether this rule will have a significant impact on small rural hospitals.

D. Regulatory Impact Analysis

1. Program Budget Effects

We have determined that implementing the provisions contained in this interim final rule will have an annual impact of $100 million or more on the economy. Thus, consistent with the requirements of E.O. 12291, we are providing a regulatory impact analysis.

As discussed in section II of the preamble to this interim final rule, section 4062(b) of Pub. L. 100–203 added section 1834(a) to the Act and established the fee schedule provisions for DME and prosthetic and orthotic devices. Subsequently, sections 6112 and 6140 of Pub. L. 101–239 and section 4152 of Pub. L. 101–508 amended various provisions of section 1834(a) of the Act. Also, section 4153(a) of Pub. L. 101–508 added section 1834(h) to the Act to establish separate payment provisions for prosthetic and orthotic devices furnished on or after January 1, 1991. The result of these successive amendments is a complex series of changes to the statutory provisions governing payments for DME and orthotics and prosthetics. We have published a succession of manual issuances to implement these changes, and carriers are now carrying out the current provisions of sections 1834 (a) and (h) of the Act. This interim final rule serves to codify the DME payment procedures that are required by statute and now in use under manual instructions.

Thus, the provisions being implemented in this document are, for the most part, specified by sections 1834 (a) and (h) of the Act. The language in sections 1834 (a) and (h) of the Act is quite precise with respect to the methods and factors to be used in determining payments for the various items of DME, prosthetics and orthotics covered under the Act, the permissible range of payments amounts for each item, and the effective dates for updating the pricing schedules. The Secretary's discretion is limited to determining the best method for administering the payment methodology and resolving technical problems that the Act does not address. Issues left to the Secretary's discretion include: The configuration of carrier service areas; the methods carriers are to use for gap-filling prices; and how carriers should compute payment for oxygen when the consumption rate falls below or exceeds the standard consumption rate within a 24-hour period. We do not believe that the discretionary aspects of this interim final rule have a significant impact on the DME payment levels.

We are unable to determine the cumulative budgetary effects of all the legislative changes described above. This is due to the fact that we cannot distinguish between differences in payment levels that have resulted from changes in market conditions since the addition of section 1834(a) of the Act in 1987, and differences that have resulted from the successive legislative changes. Instead, the projection of Medicare payment reductions displayed below reflects the changes in payment levels resulting from the amendments enacted under Pub. L. 101–508, compared to the payment levels associated with the enactment of Pub. L. 101–239. The results are as follows:

MEDICARE PROGRAM SAVINGS AS RESULT OF IMPLEMENTING PROVISIONS IN PUB. L. 101–508 RELATING TO THE PAYMENT FOR DME AND ORTHOTICS AND PROSTHETICS

[In millions][1]

FY 1992	FY 1993	FY 1994	FY 1995	FY 1996
$360	$440	$500	$560	$620

[1] Rounded to the nearest $10 million.

Short of developing an entirely different approach to paying for DME (which would require enactment of new legislation), there are no alternatives available for consideration other than implementing the payment methodology being set forth in this interim final rule.

2. General Effects

Since beneficiary copayments are linked to the level of allowed payments for DME, the reduction in fee schedule amounts will also benefit beneficiaries. The magnitude of savings to beneficiaries will coincide with the reduction in payment levels for DME. As described above, the payment levels for capped rental items of DME will be reduced, but section 4152(a) of Pub. L. 101–508 also requires reductions in payments for seat-lift chair mechanisms and TENS, and section 4152(b) will result in reductions in payment levels for all items of DME through the imposition of national payment limits. Overall, beneficiaries that require DME, orthotics or prosthetics can expect aggregate savings equal to about 25 percent of the amount the Medicare program will save.

More generally, those Medicaid State agencies that now pay on the basis of reasonable charges may adopt fee schedules similar to those being implemented in these regulations. Also, removing submitted charges as a basis for payment may result in a slowing in the rate at which prices for these items have been increasing. This could result in savings to other purchasers or renters of capped rental DME including private insurance payers. Finally, because private insurance covers only a relatively small proportion of DME expenses, with remaining expenses covered by individuals, it is possible that price competition may develop in the consumer segment of the market. If this were to occur, then it is possible that prices and rental charges for capped rental items might drop significantly. Thus, from the standpoint of the purchasers or renters of DME, orthotics, or prosthetic devices, the provisions contained in this interim final rule may result in lower medical care costs for the general population.

From the perspectives of manufacturers and distributors, the reductions in Medicare payments for DME, orthotics, and prosthetic devices will result in some revenue losses. Particularly with respect to payments for capped rental items, (as a result of the amendments to section 1834(a) of the Act made by section 4152(b)(2)(A)(10) of Pub. L. 101–508) those manufacturers and suppliers that specialize in these items may see significant reductions in their revenues for these items. The response to these losses is likely to vary based on product line concentration and the particular market conditions facing each manufacturer or distributor. We do not possess the data that would enable us to predict how manufacturers and suppliers will react. However, as noted in section A.2. of this impact analysis, total DME sales (including vision and hearing aid products, DME, orthotics, and prosthetics) in 1990 equaled $12.1 billion. Given the comparatively small size of the reductions in Medicare payments relative to the total DME market, we doubt that the impact on DME manufacturers and suppliers will significantly affect the quantity or quality of DME available to Medicare beneficiaries.

VI. Other Required Information

A. Waiver of Notice of Proposed Rulemaking

Because the Secretary is exercising some discretion in implementing section 1834(a) of the Act, we ordinarily would publish a notice of proposed rulemaking and afford a period for public comment. However, section 4039(g) of Pub. L. 100–203 expressly provides that the Secretary may issue regulations on an interim or other basis as may be necessary to implement the amendments made by Subtitle A of Pub. L. 100–203, which includes the provisions in section 4062 being implemented here. In addition, section 4207(j) of Pub. L. 101–508 gives the Secretary similar discretion in implementing its provisions. The amendments made to the Act by section 4062 of Pub. L. 100–203, and sections 4152 and 4153 of Pub. L. 101–508 entailed our creating an entirely new payment system for DME and orthotic and prosthetic devices. Under the above cited express statutory provisions allowing the Secretary to issue regulations on an interim basis, no notice and comment period is necessary prior to effectuation of these regulations. Therefore, we find good cause to waive the notice of proposed rulemaking and to issue these regulations as a final rule on an interim basis. We are providing a 60-day comment period for public comment as indicated at the beginning of this rule.

B. Public Comments

Because of the large number of items of correspondence we normally receive concerning regulations, we cannot acknowledge or respond to the comments individually. However, we will issue a final rule and respond to the comments in the preamble of that rule.

C. Paperwork Reduction Act

This rule will not impose information collection requirements; consequently, it need not be reviewed by the Executive Office of Management and Budget under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501–3511).

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 414

Durable medical equipment, End-stage renal disease (ESRD), Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements.

42 CFR chapter IV is amended as set forth below:

I. Part 405, subpart E is amended as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Subpart E—Criteria for Determination of Reasonable Charges; Radiology Fee Schedules; and Reimbursement for Services of Hospital Interns, Residents, and Supervising Physicians

A. The authority citation for subpart E is revised to read as follows:

Authority: Secs. 1102, 1814(b), 1832, 1833(a), 1834 (a) and (b), 1842 (b) and (h), 1848, 1861 (b), (v), and (aa), 1862(a)(14), 1866(a), 1871, 1881, 1886, 1887, and 1889 of the Social Security Act as amended (42 U.S.C. 1302, 1395f(b), 1395k, 1395l(a), 1395m (a) and (b), 1395u (b) and (h), 1395w–4, 1395x (b), (v), and (aa), 1395y(a)(14), 1395cc(a), 1395hh, 1395rr, 1395ww, 1395xx, and 1395zz).

B. Section 405.501 is amended by adding a new paragraph (f) to read as follows:

§ 405.501 Determination of reasonable charges.

* * * * *

(f) For services furnished on or after January 1, 1989, payment under Medicare Part B for durable medical equipment and prosthetic and orthotic devices is determined in accordance with the provisions of subpart D of part 414 of this chapter.

§ 405.514 [Removed]

C. Section 405.514 is removed.

II. Part 410 is amended as follows:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

A. The authority citation for part 410 is revised to read as follows:

Authority: Secs. 1102, 1832, 1833, 1834(a), 1835, 1861(r), (s), (aa), (cc), and (gg), 1871 and 1881 of the Social Security Act, (42 U.S.C. 1302, 1395k, 1395l, 1395m(a), 1395n, 1395x(r), (s), (aa), (cc) and (gg), 1395hh, and 1395rr).

Subpart B—Medical and Other Health Services

B. In § 410.36, the undesignated introductory text is redesignated as paragraph (a); paragraphs (a), (b), and (c) are redesignated as paragraphs (a)(1), (a)(2), and (a)(3) and are republished, and new paragraph (b) is added to read as follows:

§ 410.36 Medical supplies, appliances and devices: Scope.

(a) Medicare Part B pays for the following medical supplies, appliances and devices:

(1) Surgical dressings, and splints, casts, and other devices used for reduction of fractures and dislocations.

(2) Prosthetic devices, other than dental, that replace all or part of an internal body organ, including colostomy bags and supplies directly related to colostomy care, including—

(i) Replacement of prosthetic devices; and

(ii) One pair of conventional eyeglasses or conventional contact lenses furnished after each cataract surgery during which an intraocular lens is inserted.

(3) Leg, arm, back, and neck braces and artificial legs, arms, and eyes, including replacements if required because of a change in the individual's physical condition.

(b) As a requirement for payment, HCFA may determine through carrier instructions, or carriers may determine, that an item listed in paragraph (a) of this section requires a written physician order before delivery of the item.

C. In § 410.38, in paragraph (b), the phrase "1861(j)(1)" is revised to read "1819(a)(1)"; paragraph (c) is revised; and new paragraphs (d), (e), (f), and (g) are added to read as follows:

§ 410.38 Durable medical equipment: Scope and conditions.

* * * * *

(c) Wheelchairs may include a power-operated vehicle that may be appropriately used as a wheelchair, but only if the vehicle—

(1) Is determined to be necessary on the basis of the individual's medical and physical condition;

(2) Meets any safety requirements specified by HCFA; and

(3) Except as provided in paragraph (c)(2) of this section, is ordered in writing by a specialist in physical medicine, orthopedic surgery, neurology, or rheumatology, the written order is furnished to the supplier before the delivery of the vehicle to the beneficiary, and the beneficiary requires the vehicle and is capable of using it.

(4) A written prescription from the beneficiary's physician is acceptable for ordering a power-operated vehicle if a specialist in physical medicine, orthopedic surgery, neurology, or rheumatology is not reasonably accessible. For example, if travel to the specialist would be more than one day's trip from the beneficiary's home or if the beneficiary's medical condition precluded travel to the nearest available specialist, these circumstances would satisfy the "not reasonably accessible" requirement.

(d) Medicare Part B pays for medically necessary equipment that is used for treatment of decubitus ulcers if—

(1) The equipment is ordered in writing by the beneficiary's attending physician, or by a specialty physician on referral from the beneficiary's attending physician, and the written order is furnished to the supplier before the delivery of the equipment; and

(2) The prescribing physician has specified in the prescription that he or she will be supervising the use of the equipment in connection with the course of treatment.

(e) Medicare Part B pays for a medically necessary seat-lift if it—

(1) Is ordered in writing by the beneficiary's attending physician, or by a specialty physician on referral from the beneficiary's attending physician, and the written order is furnished to the supplier before the delivery of the seat-lift;

(2) Is for a beneficiary who has a diagnosis designated by HCFA as requiring a seat-lift; and

(3) Meets safety requirements specified by HCFA.

(f) Medicare Part B pays for transcutaneous electrical nerve stimulator units that are—

(1) Determined to be medically necessary; and

(2) Ordered in writing by the beneficiary's attending physician, or by a specialty physician on referral from the beneficiary's attending physician, and the written order is furnished to the supplier before the delivery of the unit to the beneficiary.

(g) As a requirement for payment, HCFA may determine through carrier instructions, or carriers may determine that an item of durable medical equipment requires a written physician order before delivery of the item.

III. Part 414 is amended to read as follows:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

A. The authority citation for part 414 is revised to read as follows:

Authority: Secs. 1102, 1833(a), 1834 (a) and (h), 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395l(a), 1395m (a) and (h), 1395hh and 1395rr).

B. Subpart D is amended by adding new §§ 414.200 through .222, §§ 414.226 through .229, and § 414.232 to read as follows:

Subpart D—Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices

Sec.

Subpart D—Payment for Durable Medical Equipment and Prosthetic and Orthotic Devices

§ 414.200 Purpose.

This subpart implements sections 1834 (a) and (h) of the Act by specifying how payments are made for the purchase or rental of new and used durable medical equipment and prosthetic and orthotic devices for Medicare beneficiaries.

§ 414.202 Definitions.

For purposes of this subpart, the following definitions apply:

Covered item update means the percentage increase in the consumer price index for all urban consumers (U.S. city average) (CPI–U) for the 12-month period ending with June of the previous year.

Durable medical equipment means equipment, furnished by a supplier or a home health agency that—

(1) Can withstand repeated use;

(2) Is primarily and customarily used to serve a medical purpose;

(3) Generally is not useful to an individual in the absence of an illness or injury; and

(4) Is appropriate for use in the home. (See § 410.38 of this chapter for a description of when an institution qualifies as a home.)

Prosthetic and orthotic devices means—

(1) Devices that replace all or part of an internal body organ, including ostomy bags and supplies directly related to ostomy care, and replacement of such devices and supplies;

(2) One pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens; and

(3) Leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the beneficiary's physical condition.

The following are neither prosthetic nor orthotic devices—

(1) Parenteral and enteral nutrients, supplies, and equipment;

(2) Intraocular lenses;

(3) Medical supplies such as catheters, catheter supplies, ostomy bags, and supplies related to ostomy care that are furnished by an HHA as part of home health services under § 409.40(e) of this chapter;

(4) Dental prostheses.

Region means those carrier service areas administered by HCFA regional offices.

§ 414.210 General payment rules.

(a) *General rule.* For items furnished on or after January 1, 1989, except as provided in paragraphs (c) and (d) of this section, Medicare pays for durable medical equipment, prosthetics and orthotics, including a separate payment for maintenance and servicing of the items as described in paragraph (e) of this section, on the basis of 80 percent of the lesser of—

(1) The actual charge for the item;

(2) The fee schedule amount for the item, as determined in accordance with the provisions of §§ 414.220 through 414.232.

(b) *Payment classification.* (1) The carrier determines fee schedules for the following classes of equipment and devices:

(i) Inexpensive or routinely purchased items, as specified in § 414.220.

(ii) Items requiring frequent and substantial servicing, as specified in § 414.222.

(iii) Certain customized items, as specified in § 414.224.

(iv) Oxygen and oxygen equipment, as specified in § 414.226.

(v) Prosthetic and orthotic devices, as specified in § 414.228.

(vi) Other durable medical equipment (capped rental items), as specified in § 414.229.

(vii) Transcutaneous electrical nerve stimulators (TENS), as specified in § 414.232.

(2) HCFA designates the items in each class of equipment or device through its program instructions.

(c) *Exception for certain HHAs.* Public HHAs and HHAs that furnish services or items free-of-charge or at nominal prices to a significant number of low-income patients, as defined in § 413.13(a) of this chapter, are paid on the basis of 80 percent of the fee schedule amount determined in accordance with the provision of §§ 414.220 through 414.230.

(d) *Prohibition on special limits.* For items furnished on or after January 1, 1989 and before January 1, 1991, neither HCFA nor a carrier may establish a special reasonable charge for items covered under this subpart on the basis of inherent reasonableness as described in § 405.502(g) of this chapter.

(e) *Maintenance and servicing*—(1) *General rule.* Except as provided in paragraph (e)(2) of this section, the carrier pays the reasonable and necessary charges for maintenance and servicing of purchased equipment. Reasonable and necessary charges are those made for parts and labor not otherwise covered under a manufacturer's or supplier's warranty. Payment is made, as needed, in a lump sum based on the carrier's consideration of the item. Payment is not made for maintenance and servicing of a rented item other than the maintenance and servicing fee for other durable medical equipment, as described in § 414.229(e).

(2) *Exception.* For items purchased on or after June 1, 1989, no payment is made under the provisions of paragraph (e)(1) of this section for the maintenance and servicing of:

(i) Items requiring frequent and substantial servicing, as defined in § 414.222(a);

(ii) Capped rental items, as defined in § 414.229(a), that are not purchased in accordance with § 414.229(d); and

(iii) Oxygen equipment, as defined in § 414.226.

(f) *Replacement of equipment.* Except as provided in § 414.229(g), if a purchased item of DME or a prosthetic or orthotic device paid for under this subpart has been in continuous use by the patient for the equipment's reasonable useful lifetime or if the carrier determines that the item is lost or irreparably damaged, the patient may elect to obtain a new piece of equipment.

(1) The reasonable useful lifetime of DME or prosthetic and orthotic devices is determined through program instructions. In the absence of program instructions, carriers may determine the reasonable useful lifetime of equipment but in no case can it be less than 5 years. Computation is based on when the equipment is delivered to the beneficiary, not the age of the equipment.

(2) If the beneficiary elects to obtain replacement equipment, payment is made on a purchase basis.

§ 414.220 Inexpensive or routinely purchased items.

(a) *Definitions.*

(1) *Inexpensive equipment* means equipment whose average purchase price did not exceed $150 during the period July 1986 through June 1987.

(2) *Routinely purchased equipment* means equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987.

(b) *Payment rules.* (1) Subject to the limitation in paragraph (b)(2) of this section, payment for inexpensive or routinely purchased items is made on a rental basis or in a lump-sum amount for purchase of the item based on the applicable fee schedule amount.

(2) The total amount of payments made for an item may not exceed the fee schedule amount recognized for the purchase of that item.

(c) *Fee schedule amount for 1989 and 1990.* The fee schedule amount for payment of purchase or rental of inexpensive or routinely purchased items furnished in 1989 and 1990 is the local payment amount determined as follows:

(1) The carrier determines the average reasonable charge for inexpensive or routinely purchased items that were furnished during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item. A separate determination of an average reasonable charge is made for rental equipment, new purchased equipment, and used purchased equipment.

(2) The carrier adjusts the amount determined under paragraph (c)(1) of this section by the change in the level of the CPI–U for the 6-month period ending December 1987.

(d) *Updating the local payment amounts for years after 1990.* For each year subsequent to 1990, the local payment amounts of the preceding year are increased or decreased by the covered item update. For 1991 and 1992, the covered item update is reduced by 1 percentage point.

(e) *Calculating the fee schedule amounts for years after 1990.* For years after 1990, the fee schedule amounts are equal to the national limited payment amount.

(f) *Calculating the national limited payment amount.* The national limited payment amount is computed as follows:

(1) The 1991 national limited payment amount is equal to:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts;

(ii) The sum of 67 percent of the local payment amount plus 33 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average of all local payment amounts; or

(iii) The sum of 67 percent of the local payment amount plus 33 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average of all local payment amounts.

(2) The 1992 national limited payment amount is equal to:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts;

(ii) The sum of 33 percent of the local payment amount plus 67 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average; or

(iii) The sum of 33 percent of the local payment amount plus 67 percent of 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average.

(3) For 1993 and subsequent years, the national limited payment amount is equal to:

(i) 100 percent of the local payment amount if the local payment amount is neither greater than the weighted average nor less than 85 percent of the weighted average of all local payment amounts;

(ii) 100 percent of the weighted average of all local payment amounts if the local payment amount exceeds the weighted average of all local payment amounts; or

(iii) 85 percent of the weighted average of all local payment amounts if the local payment amount is less than 85 percent of the weighted average of all local payment amounts.

§ 414.222 Items requiring frequent and substantial servicing.

(a) *Definition.* Items requiring frequent and substantial servicing in order to avoid risk to the beneficiary's health are the following:

(1) Ventilators

(2) Aspirators.

(3) Continuous and intermittent positive pressure breathing machines.

(4) Nebulizers.

(5) Continuous passive motion machines.

(6) Other items specified in HCFA program instructions.

(7) Other items identified by the carrier.

(b) *Payment rule.* Rental payments for items requiring frequent and substantial servicing are made on a monthly basis, and continue until medical necessity ends.

(c) *Fee schedule amount for 1989 and 1990.* The fee schedule amount for items requiring frequent and substantial servicing is the local payment amount determined as follows:

(1) The carrier determines the average reasonable charge for rental of items requiring frequent and substantial servicing that were furnished during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item.

(2) The carrier adjusts the amounts determined under paragraph (c)(1) of this section by the change in the level of the CPI–U for the 6-month period ending December 1987.

(d) *Updating the fee schedule amounts for years after 1990.* For years after 1990, the fee schedules are determined using the methodology contained in paragraphs (d), (e), and (f) of § 414.220.

§ 414.226 Oxygen and oxygen equipment.

(a) *Payment rules.* (1) Payment for rental of oxygen equipment and purchase of oxygen contents is made based on a monthly fee schedule amount.

(2) Monthly fee schedule payments continue until medical necessity ends.

(b) *Monthly fee schedule amount.* (1) Monthly fee schedule amounts are separately calculated for the following items:

(i) Stationary oxygen equipment and oxygen contents (stationary and portable oxygen contents).

(ii) Portable oxygen equipment only.

(iii) Stationary and portable oxygen contents only.

(iv) Portable oxygen contents only.

(2) For 1989 and 1990, the monthly fee schedule amounts are the local payment amounts determined as follows:

(i) The carrier determines the base local average monthly payment rate equal to the total reasonable charges for the item for the 12-month period ending December 1986 divided by the total number of months for all beneficiaries receiving the item for the same period. In determining the local average monthly payment rate, the following limitations apply:

(A) Purchase charges for oxygen systems are not included as items classified under paragraph (b)(1)(i) of this section.

(B) Purchase charges for portable equipment are not included as items classified under paragraph (b)(1)(ii) of this section.

(ii) The carrier determines the local monthly payment amount equal to 0.95 times the base local average monthly payment amount adjusted by the change in the CPI–U for the six-month period ending December 1987.

(3) For years after 1990, the fee schedule amounts are determined using the methodology contained in § 414.220 (d), (e), and (f).

(c) *Application of monthly fee schedule amounts.* (1) The fee schedule amount for items described in paragraph (b)(1)(i) of this section is paid when the beneficiary rents a stationary oxygen system.

(2) Subject to the limitation set forth in paragraph (d)(2) of this section, the fee schedule amount for items described in paragraph (b)(1)(ii) of this section is paid when the beneficiary rents a portable oxygen system.

(3) The fee schedule amount for items described in paragraph (b)(1)(iii) of this section is paid when the beneficiary owns a stationary gaseous or liquid oxygen system.

(4) The fee schedule amount for items described in paragraph (b)(1)(iv) of this section is paid when the beneficiary owns or rents a portable gaseous or portable liquid oxygen system and uses either a stationary oxygen concentrator or no stationary oxygen system.

(d) *Volume adjustments:* (1) The fee schedule amount for an item described in paragraph (b)(1)(i) of this section is adjusted as follows:

(i) If the attending physician prescribes an oxygen flow rate exceeding four liters per minute, the fee schedule amount is increased by 50 percent, subject to the limit in paragraph (d)(2) of this section.

(ii) If the attending physician prescribes an oxygen flow rate of less than one liter per minute, the fee schedule amount is decreased by 50 percent.

(2) If portable oxygen equipment is used and the prescribed oxygen flow rate exceeds four liters per minute, the total fee schedule amount recognized for payment is limited to the higher of—

(i) The sum of the monthly fee schedule amount for the items described in paragraphs (b)(1) (i) and (ii) of this section; or

(ii) The adjusted fee schedule amount described in paragraph (d)(1)(i) of this section.

(3) In establishing the volume adjustment for those beneficiaries whose physicians prescribe varying flow rates, the following rules apply:

(i) If the prescribed flow rate is different for stationary oxygen equipment than for portable oxygen equipment, the flow rate for the stationary equipment is used.

(ii) If the prescribed flow rate is different for the patient at rest than for the patient at exercise, the flow rate for the patient at rest is used.

(iii) If the prescribed flow rate is different for nighttime use and daytime use, the average of the two flow rates is used.

§ 414.228 Prosthetic and orthotic devices.

(a) *Payment rule.* Payment is made on a lump-sum basis for prosthetic and orthotic devices subject to this subpart.

(b) *Fee schedule amounts.* The fee schedule amount for prosthetic and orthotic devices is determined as follows:

(1) The carrier determines a base local purchase price equal to the average reasonable charge for items purchased during the period July 1, 1986 through June 30, 1987 based on the mean of the carrier's allowed charges for the item.

(2) The carrier determines a local purchase price equal to the following:

(i) For 1989 and 1990, the base local purchase price is adjusted by the change in the level of the CPI–U for the 6-month period ending December 1987.

(ii) For 1991 through 1993, the local purchase price for the preceding year is adjusted by the applicable percentage increase for the year. The applicable percentage increase is equal to 0 percent for 1991 and for subsequent years, is equal to the percentage increase in the CPI–U for the 12-month period ending with June of the previous year.

(3) HCFA determines the regional purchase price equal to the following:

(i) For 1992, the average (weighted by the relative volume of all claims among carriers) of the local purchase prices for the carriers in the region.

(ii) For 1993 and subsequent years, the regional purchase price for the preceding year adjusted by the applicable percentage increase for the year.

(4) HCFA determines a purchase price equal to the following:

(i) For 1989, 1990 and 1991, 100 percent of the local purchase price.

(ii) For 1992, 75 percent of the local purchase price plus 25 percent of the regional purchase price.

(iii) For 1993, 50 percent of the local purchase price plus 50 percent of the regional purchase price.

(iv) For 1994 and subsequent years, 100 percent of the regional purchase price.

(5) For 1992 and subsequent years, HCFA determines a national average purchase price equal to the unweighted average of the purchase prices determined under paragraph (b)(4) of this section for all carriers.

(6) HCFA determines the fee schedule amount equal to 100 percent of the purchase price determined under paragraph (b)(4) of this section, subject to the following limitations:

(i) For 1992, the amount cannot be greater than 125 percent nor less than 85 percent of the national average purchase price determined under paragraph (b)(5) of this section.

(ii) For 1993 and subsequent years, the amount cannot be greater than 120 percent of the national average nor less than 90 percent of the national average purchase price determined under paragraph (b)(5) of this section.

§ 414.229 Other durable medical equipment—Capped rental items.

(a) *General payment rule.* Subject to the limitation set forth in paragraph (b) of this section, payment is made on a rental or purchase option basis for other durable medical equipment that is not subject to the payment provisions set forth in §§ 414.220 through 414.228.

(b) *Fee schedule amounts for rental.* (1) For 1989 and 1990, the monthly fee schedule amount for rental of other covered durable medical equipment equals 10 percent of the purchase price recognized as determined under paragraph (c) of this section subject to the following limitation: For 1989 and 1990, the fee schedule amount cannot be greater than 115 percent nor less than 85 percent of the prevailing charge, as determined under § 405.504 of this chapter, established for rental of the item in January 1987, as adjusted by the change in the level of the CPI–U for the 6-month period ending December 1987.

(2) For 1991 and subsequent years, the monthly fee schedule amount for rental of other covered durable medical equipment equals 10 percent of the purchase price recognized as determined under paragraph (c) of this section for each of the first 3 months and 7.5 percent of the purchase price for each of the remaining months.

(c) *Determination of purchase price.* The purchase price of other covered durable medical equipment is determined as follows:

(1) For *1989 and 1990.* (i) The carrier determines a base local purchase price amount equal to the average of the purchase prices submitted on an assignment-related basis of new items supplied during the 6-month period ending December 1986.

(ii) The purchase price is equal to the base local purchase price adjusted by the change in the level of the CPI–U for the 6-month period ending December 1987.

(2) For *1991.* (i) The local payment amount is the purchase price for the preceding year adjusted by the covered item update for 1991 and decreased by the percentage by which the average of the reasonable charges for claims paid for all other items described in § 414.229, is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988.

(ii) The purchase price for 1991 is the national limited payment amount as

determined using the methodology contained in § 414.220(f).

(3) For *years after 1991*. The purchase price is determined using the methodology contained in paragraphs (d) and (e) of § 414.220.

(d) *Purchase option*. Suppliers must offer a purchase option to beneficiaries during the 10th continuous rental month and, for power-driven wheelchairs, the purchase option must also be made available at the time the equipment is initially furnished.

(1) Suppliers must offer beneficiaries the option of purchasing power-driven wheelchairs at the time the supplier first furnishes the item. Payment must be on a lump-sum fee schedule purchase basis if the beneficiary chooses the purchase option. The purchase fee is the amount established in § 414.229(c).

(2) Suppliers must offer beneficiaries the option of converting capped rental items (including power-driven wheelchairs not purchased when initially furnished) to purchased equipment during their 10th continuous rental month. Beneficiaries have one month from the date the supplier makes the offer to accept the purchase option.

(i) If the beneficiary does not accept the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 15 months. After 15 months of rental payments have been paid, the supplier must continue to provide the item without charge, other than a charge for maintenance and servicing fees, until medical necessity ends or Medicare coverage ceases. A period of continuous use is determined under the provisions in § 414.230.

(ii) If the beneficiary accepts the purchase option, payment continues on a rental basis not to exceed a period of continuous use of longer than 13 months. On the first day after 13 continuous rental months during which payment is made, the supplier must transfer title to the equipment to the beneficiary.

(e) *Payment for maintenance and servicing*. (1) The carrier establishes a reasonable fee for maintenance and servicing for each rented item of other durable medical equipment. The fee may not exceed 10 percent of the purchase price recognized as determined under paragraph (c) of this section.

(2) Payment of the fee for maintenance and servicing of other durable medical equipment that is rented is made only for equipment that continues to be used after 15 months of rental payments have been made and is limited to the following:

(i) For the first 6-month period, no payments are to be made.

(ii) For each succeeding 6-month period, payment may be made during the first month of that period.

(3) Payment for maintenance and servicing DME purchased in accordance with paragraphs (d)(1) and (d)(2)(ii) of this section, is made on the basis of reasonable and necessary charges.

(f) *Transition to the fee schedules*. For purposes of computing the 10-month or 15-month period of continuous use for other durable medical equipment, as described in § 414.230, the carrier counts the first month that the beneficiary continuously rented the equipment without regard to whether that month occurred before January 1, 1989 or after. If a beneficiary's 15-month rental period ends prior to January 1, 1989, no further purchase or rental payments are to be made except for maintenance and servicing of equipment as described in paragraph (e) of this section.

(g) *Replacement of equipment*. If the item of equipment has been in continuous use by the patient on either a rental or purchase basis for the equipment's useful lifetime, or if the carrier determines that the item is lost or irreparably damaged, the patient may elect to obtain a new piece of equipment.

(1) The reasonable useful lifetime of DME or prosthetic and orthotic devices is determined through program instructions. In the absence of program instructions, carriers may determine the reasonable useful lifetime of equipment but in no case can it be less than 5 years. Computation is based on when the equipment is delivered to the beneficiary, not the age of the equipment.

(2) If the beneficiary elects to obtain replacement equipment, payment is made on a rental or purchase basis in accordance with paragraph (a) of this section or on a lump-sum purchase basis if a purchase agreement had been entered into in accordance with paragraph (d) of this section.

§ 414.232 Special payment rules for transcutaneous electrical nerve stimulators (TENS).

(a) *General payment rule*. Except as provided in paragraph (b) of this section, payment for TENS is on a purchase basis with the purchase price determined using the methodology for purchase of inexpensive or routinely purchased items as described in § 414.220. Effective for TENS furnished on or after April 1, 1990, the payment amount computed in § 414.220(c)(2) is reduced by 15 percent. Effective January 1, 1991, the payment amount is further reduced by an additional 15 percent.

(b) *Exception*. In order to permit an attending physician time to determine whether the purchase of the TENS is medically appropriate for a particular patient, two months of rental payments may be made in addition to the purchase price. The rental payments are equal to 10 percent of the purchase price.

(Catalog of Federal Domestic Assistance Program No. 93.774 Medicare—Supplementary Medical Insurance Program)

Dated: July 13, 1992.

William Toby,

Acting Administrator, Health Care Financing Administration.

Approved: August 7, 1992.

Louis W. Sullivan,

Secretary.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 675

[Docket No. 911172-2021]

Groundfish of the Bering Sea and Aleutian Islands Area

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Change in recordkeeping and reporting requirements; change in observer coverage.

SUMMARY: NMFS is requiring that Daily Production Reports be submitted by processor vessels and shoreside processing facilities that catch or receive groundfish under any Western Alaska Community Development Quota (CDQ) allocation. In addition, NMFS announces that all vessels and shoreside processing facilities must have a NMFS certified observer present when engaged in fishing for or receiving groundfish from CDQs, except catcher vessels delivering only unsorted codends to observed motherships. These actions are necessary to prevent exceeding each allocated CDQ.

EFFECTIVE DATES: 12 noon, Alaska local time (A.l.t.), December 2, 1992, through 12 midnight, A.l.t., December 31, 1992.

FOR FURTHER INFORMATION CONTACT: Martin Loeffled, Resource Management Specialist, NMFS, 907-586-7228.

SUPPLEMENTARY INFORMATION: The groundfish fishery in the Bering Sea/Aleutian Islands (BASI) exclusive economic zone is managed by the

Secretary of Commerce according to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson Fishery Conservation and Management Act. Fishing by U.S. vessels is governed by regulations implementing the FMP at 50 CFR parts 620 and 675.

The CDQ program was created to help develop commercial fisheries in communities on the Bering Sea coast. Qualifying communities are assigned a portion of the overall program allocation. Each of these portions represents a relatively small quota, which must be individually monitored. It is expected that the size of each CDQ will result in a fishery of short duration. The combination of several CDQs, each varying in quota amounts and proposed effort, necessitates additional reporting and observer coverage requirements to manage the fisheries effectively.

The Director of the Alaska Region, NMFS (Regional Director), in accordance with § 675.5(c)(3)(i), is requiring processor vessels and shoreside processing facilities that conduct fishing activities in, or receive groundfish from, any CDQ fishery in the BSAI management area to submit Daily Production Reports in addition to weekly processor reports.

Daily Production Reports must include the information required by § 675.5(c)(3)(ii). Processors must submit the required information on the "Alaska Groundfish Processor Daily Production Report" form available in the processors' recordkeeping reference manual or from the Regional Director. Processors must transmit their completed Daily Production Reports to the Regional Director by facsimile transmission to number (907) 586–7131, by telephone via number (907) 586–7228, or by telex (U.S. code) at 622–9600 no later than 12 hours after the end of the day the groundfish was processed. When all CDQ fisheries are completed, the Regional Director will rescind the requirement for Daily Production Reports.

As authorized under §§ 675.25 (c)(1)(i) and (c)(2)(i), NMFS is requiring that all vessels and shoreside processing facilities have a NMFS certified observer present when engaged in fishing for or receiving groundfish from CDQs, except catcher vessels delivering only unsorted codends to observed motherships.

Classification

This action is taken under §§ 675.5 and 675.25 and complies with Executive Order 12291.

The Assistant Administrator for Fisheries, NOAA, finds that reasons justifying promulgation of this action also make it impracticable and contrary to the public interest to provide notice and opportunity for prior comment or to delay for 30 days its effective date under sections 553 (b) and (d) of the Administrative Procedure Act. CDQ fishing effort without 100 percent observer coverage and Daily Production Reports could result in exceeding the individual CDQ allotments.

The collection-of-information requirement contained in this notice was approved by the Office of Management and Budget (OMB) as a revision to OMB No. 0648–213 (56 FR 9636; March 7, 1991).

List of Subjects in 50 CFR Part 675

Fisheries, Reporting and recordkeeping requirements.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 1, 1992.

David S. Crestin,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

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